

4-2010

Safe Medicine Disposal for ME A Handbook and Summary Report

Lenard W. Kaye

University of Maine, len.kaye@maine.edu

Jennifer Crittenden

The University of Maine, jennifer.crittenden@maine.edu

Stevan Gressitt

Maine Office of Adult Mental Health

Follow this and additional works at: https://digitalcommons.library.umaine.edu/moca_service



Part of the [Community Health and Preventive Medicine Commons](#), [Gerontology Commons](#), [Health Policy Commons](#), [Policy Design, Analysis, and Evaluation Commons](#), [Policy History, Theory, and Methods Commons](#), [Public Health Education and Promotion Commons](#), [Public Policy Commons](#), and the [Rural Sociology Commons](#)

Repository Citation

Kaye, Lenard W.; Crittenden, Jennifer; and Gressitt, Stevan, "Safe Medicine Disposal for ME A Handbook and Summary Report" (2010). *Maine Center on Aging Service and Consultation*. 1.

https://digitalcommons.library.umaine.edu/moca_service/1

This Report is brought to you for free and open access by DigitalCommons@UMaine. It has been accepted for inclusion in Maine Center on Aging Service and Consultation by an authorized administrator of DigitalCommons@UMaine. For more information, please contact um.library.technical.services@maine.edu.

Reducing Prescription Drug Misuse
Through the Use of a Citizen Mail-Back Program
in Maine

Safe Medicine Disposal for ME A Handbook and Summary Report



Funded by the U.S. EPA Grant # CH-83336001-0

Lenard Kaye, Principal Investigator
Jennifer Crittenden, Program Manager
University of Maine Center on Aging
Bangor, ME

Stevan Gressitt, Co-Principal Investigator
Maine Office of Adult Mental Health
Maine Department of Health and Human Services
Augusta, ME

Handbook development:

Marcella Sorg, Evaluator and Consultant
Sharon LaBrie, Evaluation Assistant
Margaret Chase Smith Policy Center
University of Maine, Orono

April 2010

April 8, 2010

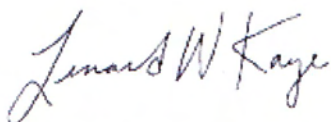
It is our pleasure to present the report on U.S. EPA Grant CH-83336001-0. It is an honor to have been selected to carry out the work on this project, which represents the first report on sampled data from the first statewide unused medicine mail-back program in the country. Funds from this grant have facilitated the development of process parameters and interpretation of rules and regulations; they have been used to initiate model agreements that we have specifically tested for reuse in other geographic or non-geographic distribution models. The range of organizations that have become engaged has grown throughout the project; the degree of support in the press and in public forums has increased as well.

We have met the goals we contracted to meet, and have also identified that there is a national need for such a program to be brought to the public as soon as possible. We believe that this project could serve as a model and suggest that findings from Phases I & II can provide informed recommendations for the future. There are implications for health care policy, as exemplified by the State of Maine adopting pharmacy regulations to reduce waste, and CMS issuing a request for comment for a similar Medicare Part D approach. We believe there are significant lessons for adherence, compliance, concordance, and improving patient outcomes from this project that have not been in general consideration before. There are implications for environmental policy in looking at relative risks, and for law enforcement in looking at how to reduce both supply of, and demand for, illicit drugs. We believe that other benefits exist including pollution prevention, but the removal of the unused medication from risk for misuse has an inestimable value if only one life is saved from overdose or accidental poisoning.

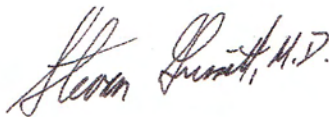
A proposal resulting from this project is the recommendation and invitation we make that the program be continued and expanded, and plans developed for replication in the immediate future. We hope we have made a significant contribution to the environmental as well as public health of the country.

Thank you for the opportunity to have carried out this project.

Respectfully,



Lenard W. Kaye, DSW/PhD
Principal Investigator



Stevan Gressitt, MD
Co-Principal Investigator



Jennifer Crittenden, MSW
Program Manager

TABLE OF CONTENTS

| | |
|--|-----------|
| TABLE OF CONTENTS..... | 2 |
| ACKNOWLEDGEMENTS..... | 3 |
| INTRODUCTION..... | 6 |
| Why Collect Unused Pharmaceuticals?..... | 7 |
| What Is The Best Way To Dispose Of Medicines? | 10 |
| How to Use This Handbook..... | 11 |
| BUILDING A SOLID FOUNDATION..... | 13 |
| Engaging Stakeholders: Community, Academic, and Government..... | 13 |
| Meeting the Challenges of a Rural and Aging State | 14 |
| Selecting an Environmentally Sound and Legally Secure System | 14 |
| Political Will and Partnerships..... | 15 |
| Partnering with Law Enforcement is a Key Component | 17 |
| Selecting a Central Coordinating Agency | 17 |
| Developing Organization Capacity..... | 18 |
| Developing a Program Mission..... | 18 |
| Goals, Objectives and Outcomes | 19 |
| Maine’s Goals and Objectives | 20 |
| THE BASICS OF THE PROGRAM..... | 23 |
| Why Maine Mailback Participants Use the Program..... | 23 |
| Refining the Concept: The Mail-Back Model | 24 |
| The Bottom Line: Costs and Funding..... | 26 |
| The Mailer | 32 |
| The Mail System & The USPS | 33 |
| When The Mailers Come In, Then What? | 34 |
| Disposal Mechanics..... | 36 |
| Volunteer Workforce: Elder Involvement is a Critical Component | 37 |
| Communication Systems | 39 |
| Feedback Loops: Tracking and Evaluation | 40 |
| Public Relations and Marketing..... | 41 |
| Effective Use of the Media..... | 42 |
| The Value of Research..... | 43 |
| What We Have Discovered with Our Program Research | 44 |
| APPENDICES..... | 62 |

ACKNOWLEDGEMENTS

First and foremost, on behalf of the University of Maine Center on Aging, we would like to acknowledge the energy and commitment that our Advisory Board Members, Community Advisory Board Members, program volunteers, and program partners have contributed to developing and implementing the mail-back program in Maine. Organizations and people that contributed to constructing and carrying out this program include:

Ahmed Abdelmageed, Director of Experiential Learning, School of Pharmacy, Husson University

Melissa Adle, Research Assistant, UMaine Center on Aging

Pat Archer, United States Postal Service

Beverley Bartlett, community member and program volunteer, Blue Hill, Maine

Deb Brucker, Maine Office of Substance Abuse

Ray Bullman, Executive Vice President, National Council on Patient Information and Education (NCPPIE)

Paula Burnett, Director, UMaine Center on Aging RSVP program

Doug Carr, Rite Aid

John Cavendish, U.S. Drug Enforcement Administration

Jason Charland, Program Associate, Center on Aging

Janine Collins, Maine Drug Enforcement Agency

Guy Cousins, Director, Maine Office of Substance Abuse

Jennifer Crittenden, Program Manager, University of Maine Center on Aging

Curt Cyr, Associate Dean, University of New England College of Pharmacy

Sue Davis, community member and program volunteer, Bucksport, Maine

Lynn DeGrenier, community member and program volunteer, Bangor, Maine

Ron Garey, United States Postal Service

Jenny Garret, Aroostook Area Agency on Aging RSVP

Don Gauthier, United States Postal Service

Derrick Grant, Maine Office of Elder Services

Stevan Gressitt, Medical Director and Co-Principal Investigator, Maine Office of Adult Mental Health Services

Terry Grover, United States Postal Service

Brenda Harvey, Commissioner, Maine Department of Health and Human Services

Lorne Herszkowicz, Polyair Manufacturing
Rebecca Hillman, United States Postal Service
Kim Johnson, Director, Maine Office of Substance Abuse
Robert Jones, Intern, UMaine Center on Aging
Anne Jordan, Commissioner, Maine Department of Public Safety
Lenard Kaye, Director and Principal Investigator, UMaine Center on Aging
Kerry Kenney, community member and pharmacist, Wells, Maine
Sharon LaBrie, Communications Coordinator, Margaret Chase Smith Policy Center
Rod Larson, Dean, School of Pharmacy, Husson University
David Littell, Commissioner, Maine Department of Environmental Protection
Chris Longley, community member and program volunteer, Albany Township, Maine
Henry Lunn, community member and program volunteer, Camden, Maine
Isabelle Markley, community member and program volunteer, Waterville, Maine
Chevelle Marshall, Program Coordinator, UMaine Center on Aging RSVP
Helen Marston, community member and program volunteer, Tenants Harbor, Maine
Nancy Matulis, community members and program volunteer, Dover-Foxcroft, Maine
Paul Matulis, community members and program volunteer, Dover-Foxcroft, Maine
Steve Mazziotti, Maine Drug Enforcement Agency
Wesley McFarlin, Intern, UMaine Center on Aging
Roy McKinney, Director, Maine Drug Enforcement Agency
Barbara Miller, community member and program volunteer, Hollis, Maine
Bill Miller, Pharmacist and Owner, Miller Drug
Matthew Mireles, President and CEO, Community Medical Foundation for Patient Safety
Dick Moskal, United States Postal Service
Barbara Nathanson, community member and program volunteer, Northport, Maine
Bert Olsen, United State Postal Service
Patricia Ott, Director, Penquis Coastal RSVP
Barbara Payne, community member and program volunteer, South Paris, Maine
Anne Perry, Representative, District 31, Maine House of Representatives

Ann Pistell, Environmental Specialist, Maine Department of Environmental Protection

Eleanor Reese, Director, Aroostook RSVP

Betty Rinehart, community member and program volunteer, Caribou, Maine

Emory Robotham, Intern, UMaine Center on Aging

Steve Rowe, Maine Attorney General

Lynette Roy, Intern, UMaine Center on Aging

Paula Silsby, Maine's U.S. Attorney General

Karen Simone, Director, Northern New England Poison Center

Elizabeth Smith, Founder and Chairman, Community Medical Foundation for Patient Safety

Marcella Sorg, Research Associate, Margaret Chase Smith Policy Center

Ruth St. Amand, Director, Healthreach RSVP

Milton Stein, Miller Drug

Kathy Sykes, Program Officer, U.S. EPA Aging Initiative

Alice White, community member and program volunteer, Winter Harbor, Maine

INTRODUCTION

The Safe Medicine Disposal for ME (SMDME) program is a statewide model for the disposal of unused household medications using a mail-back return envelope system. Established through state legislation and implemented in 2007 with a grant from the U.S. Environmental Protection Program's Aging Initiative, the program is authorized to handle both controlled and non-controlled medications (see appendix group 4 for historical documents related to the program). This handbook describes the program components, as well as the outcomes and lessons learned from Phases I & II of the program. The handbook is designed as a guide to organizations that are implementing similar programs in other states.

Maine, which has a combination of rural regions and urban centers, serves as an ideal state in which to test distribution and collection methods, combined with cost containment. The pilot program began with 11 participating pharmacies, and has since expanded to include approximately 150 pharmacies and health and human services agencies in all 16 counties of Maine. The program has broadened from the original target audience of older adults and caregivers to include adults of all ages. The program currently maintains a waiting list of interested community-based distribution sites.

The mail-back program, during its first two phases of operation, has disposed of more than 2,300 lbs of drugs, representing 3,926 envelopes. Pharmacist and pharmacy tech volunteers have cataloged and inventoried those envelopes through eight cataloging events during the first two phases of the program. The volume was so great that the inventory method was changed to a 20% sampling process during the second year of operation.

Why Collect Unused Pharmaceuticals?

The Athens Declaration,¹ developed in 2007 at the 2nd International Conference on the Environment in Athens, Greece, supported six reasons for citizens to tackle unused drug disposal: (1) to curtail childhood overdoses; (2) to restrict household drug theft; (3) to limit accumulation of drugs by the elderly; (4) to protect our physical environment; (5) to restrain improper international drug donations; and (6) to eliminate waste in the

international health care systems of all countries.

The Athens Declaration (see appendix)

Rationale for citizen unused drug disposal

- To curtail childhood overdoses
- To restrict household drug theft
- To limit accumulation of drugs by the elderly
- To protect our physical environment
- To restrain improper international drug donations
- To eliminate waste in the international health care systems of all countries

Any or all of the Athens Declaration reasons could be adopted as program goals for a mail-back drug return program. Goals should state in general terms what the program aims are, and what impact you hope to have. The Athens Declaration components describe a hoped-for result, but state it in a general (not objectified) fashion.

The Pharmaceutical Manufacturers' Association estimates that more than 3.6 billion prescriptions are written each year in the United States.² More recent figures indicate that U.S. sales of prescription medicines rose 5.1 percent in 2009 to \$300.3 billion.³ In Maine, more than 16 million prescriptions were filled in 2008,⁴ including 2.3 million

¹ The Athens Declaration can be found at <http://www.mainebenzo.org/athensdeclaration.htm>. The Declaration refers to two World Health Organization documents, the WHO Guidelines on Drug Donations and the WHO Guidelines on Drug Disposal, which are also referenced at this web address.

² Pharmaceutical Manufacturers Association, Frequently Asked Questions, accessed December 21, 2009, (http://www.phrma.org/frequently_asked_questions)

³ The Star-Ledger, Prescription drug sales rise 5.1 percent in 2009, accessed April 2, 2010, (http://www.nj.com/business/index.ssf/2010/04/prescription_drug_sales_rise_5.html)

⁴ United States: Prescription Drugs, Compare United States to Maine, accessed December 21, 2009 (<http://www.statehealthfacts.org/profileind.jsp?cmprgn=21&cat+5&rgn=1&sub=66>)

prescriptions for controlled drugs,⁵ or 157 million dosage units. Yet, research indicates that patients very frequently do not take prescribed medications as they were directed, if at all.^{6,7}

Yet, research indicates that patients very frequently do not take prescribed medications as they were directed, if at all.

In Maine, diverted, abused, and misused prescription drugs are a major cause of accidental poisonings and arrests. In 2008, 95% of Maine drug deaths were caused by pharmaceutical drugs, either alone or in combination with other drugs.⁸ The state has seen arrest rates for prescription drug-related offenses rise from 50 in 1998 to 75 in 2003, and 259 (39% of all arrests) in 2008.⁹ According to data from the 2008 National Drug Intelligence Center's National Drug Threat Survey, the state of Maine ranks number one in the country in terms of the perceived relationship of pharmaceuticals to violent crime and property crime, and second in terms of the availability of pharmaceuticals for abuse. Forty percent of Maine law enforcement agencies perceive prescription drug misuse as the most serious drug threat.¹⁰

Medication safety affects all ages. For youth, one of the fastest growing trends nationally in teenage prescription drug abuse is the “pharm party” where teens dump bottles of prescription medications they have found into a punch bowl to be distributed like candy. According to results from the 2006 Maine Youth Drug and Alcohol Use (MYDAUS) Survey, 12% of teenagers in grades 6 through 12 across the state report

⁵ Maine Prescription Monitoring Program, “PMP Prescription Count Trends within Counties,” (<http://www.maine.gov/dhhs/osa/data/pmp/reports.htm>), accessed December 21, 2009.

⁶ Sabate, E. (ed.) Adherence to Long Term Therapies: Evidence for Action. World Health Organization. Geneva, 2003.

⁷ Osterberg, L and T. Blaschke, “Adherence to medication,” New England Journal of Medicine 353:487-97, 2005.

⁸ Personal communication, MH Sorg, Rural Drug and Alcohol Research Program, Margaret Chase Smith Policy Center, University of Maine.

⁹ Sorg, MH (forthcoming) Patterns and Trends of Drug Abuse in Maine. In *Epidemiologic Trends in Drug Abuse: Proceedings of the Community Epidemiology Work Group*, June 2009. National Institute on Drug Abuse.

¹⁰ Testimony presented at the Hearing on HP0557, LD 821, An Act To Support Collection and Proper Disposal of Unwanted Drugs, April 14, 2009.

experimenting with prescription drugs, and 1 in 5 Maine youth in grades 9-12 report having used a prescription drug not prescribed to them to get high.

For older adults, persons 65 and older represent 13% of the U.S. population yet consume about a third of prescriptions sold.¹¹ Older patients also have the lowest prescription drug compliance rates of any age, including never filling their prescription, filling but not taking the prescription, taking only part of the doses, or taking less than the prescribed dose.¹² These behaviors occur in all age groups, not just elders, and result in an accumulation of medications in the household.

The large, accumulating volume of unused pharmaceuticals not only poses potential dangers to communities and to the environment,¹³ it also represents a significant over-expenditure of health care dollars. Pharmaceutical drug residues have been found in many environmental contexts, including our sewer systems and our drinking water.¹⁴ In a recent study by the Maine Department of Environmental Protection (MDEP), pharmaceuticals and personal care products (PPCPs) were found in 18 out of 19 samples of Maine water samples,¹⁵ with a majority of sites having three or more types of PPCPs present.

Although research clearly shows the presence of pharmaceuticals and other personal care products in our water supply, the effects of these exposures on the environment will depend on many factors, including the specific chemicals involved and the variation in their effects on different organisms. One topic that is of concern to some scientists is the impact on reproduction processes.

¹¹ Prescription Drug Abuse Statistics. www.prescriptiondrugabuse.us/statistics-facts.html, accessed December 21, 2009.

¹² Kocurek, B., "Promoting medication adherence in older adults...and the rest of us. *Diabetes Spectrum* 22:80-84, 2008.

¹³ Daughton, C. "Drug disposal: Ramifications for the environment and human health." U.S. Environmental Protection Agency, Drug Disposal, Pharmaceutical and Personal Care Products. (<http://www.epa.gov/ppcp/projects/disposal.html>), accessed December 21, 2009.

¹⁴ Ruhoy, I.S. and C.G. Daughton, "Types and quantities of leftover drugs entering the environment via disposal to Sewage-Revealed by coroner records," *Sci. Total Environ.* 388(1-3):137-148, 2007, also available at (<http://www.epa.gov/newlesd1/bios/daughton/SOTE2007.pdf>)

¹⁵ Littell, D.P. (2007) "Waste Pharmaceuticals: The Road Forward," Maine DEP. Conference Presentation, Improving Patient Safety through Informed Medication Prescribing and Disposal Practices, Fourth Annual Unused Drug Return Conference, (http://www.mainebenzo.org/documents/WastePharmaceuticalOct07_001.pdf).

More research is needed to clarify both the short term and long term impacts on humans. In addition, research is needed to document the costs and benefits of various interventions. This project contributes to the ongoing discussion.

What Is The Best Way To Dispose Of Medicines?

Several basic methods are currently being used in the United States to dispose of unused medicines: flushing, throwing away and collecting. These approaches are reviewed in the Appendix in a document prepared by the Northern New England Poison Center (see the Medication Disposal Summary Report in Appendix Group 4). Opinions about the best method for drug disposal vary widely. Benefits and costs of each method are different, and state legislatures have addressed these issues in different ways. The most important goals that concerned citizens and legislatures focus on are (1) preventing poisoning, (2) preventing drug abuse, (3) ensuring the safety of patients, and (4) limiting environmental impacts.

The method described in this handbook involves a statewide effort to collect drugs using a mail-back system, followed by high temperature incineration. This method has the advantages of preventing unintentional poisonings, preventing access to medicines by drug abusers, and limiting impact on the

Medication Disposal Goals

1. Prevent poisoning
2. Prevent drug diversion & abuse
3. Ensure patient safety
4. Limit environmental damage

environment. It is not as immediately inexpensive to the community, or as convenient, as throwing away or flushing. However, throwing away and flushing may create long term environmental costs that communities may have to bear in the future.

The mail-back mechanism has the advantage of being continuously available to community members. Compared to event-type community take-backs, the mail-back program does not contribute to hoarding medicines between take-back events, which might set the stage for diversion or poisonings.

Mail-back programs incur immediate costs, involve substantial program management, and still require law enforcement collaboration as do other models. These costs should be balanced against the estimated costs of future environmental damage, as well as the societal costs of drug diversion and poisoning.

An additional cost factor to consider is the drug waste within our medical system. Medication accumulates in households because too much, or the wrong drug was prescribed; patients did not take the drugs, or did not take them as directed. These effects point to the importance of careful prescription management and patient education at the front end.

How to Use This Handbook

This handbook was produced as a general guide to organizations interested in developing a mail-back program in their state, region, corporate or affinity group. It is not meant as a step-by-step manual. Each state's laws and cultural context are unique. For example, responses and participation by particular stakeholders, such as law enforcement agencies, will vary greatly. Additionally, ideas about prescription drug return programs will have evolved since work began on this project two years ago. There must be recognition that Federal law and regulations has played a major role in shaping, and at times constraining, certain aspects of the mailback program design.

Thus, we have provided an overview of the principles and guidelines to serve as a concept umbrella. Readers will find more specific material in the appendices. These documents may be of assistance as new programs are developed and the guidelines are being implemented.

Helpful Appendices Included:

- Contact information for program leadership
- Organizations (state, federal, national, and international) that were involved, to provide ideas about stakeholders to include
- A detailed project conceptual timeline to assist in planning
- Legal and technical documents and agreements that link the project with multiple stakeholders
- Sample distribution site materials
- Helpline and volunteer information
- Instruction booklet for preparing and returning medicine
- Marketing and outreach materials

BUILDING A SOLID FOUNDATION

“A major reason we went with a mail-back program is that we’re the third most rural state in the nation, our population is very dispersed, and we have a significant prescription drug problem. We believed mail-back programming might be the most convenient and the least cumbersome method to use. We not only considered rurality issues, but also considered the vulnerability of populations who are less mobile, and less physically able to transport medications from one point to another.”

Lenard Kaye, D.S.W, Ph.D, Director and Professor,
University of Maine Center on Aging

Engaging Stakeholders: Community, Academic, and Government

By the time the proposal to pilot the Maine mail-back program was written in 2007, a wide range of stakeholders had been engaged for several years in discussions with policy makers about Maine’s prescription drug problem generally. A coalition, initially convened by the Maine Benzodiazepine Study Group (MBSG) and the Maine Drug Enforcement Agency (MDEA), began to consider drug return programs as one solution beginning in 2002.

Stakeholders were included in these discussions from children’s advocacy, substance abuse treatment, law enforcement, environmental organizations, medical associations, university research programs, as well as legislators and other policy makers. Every effort was made to come to informal consensus as the work proceeded. Communication with Federal agencies was initiated early on in the process for general guidance and to ensure clarification of existing regulations.

Detailed discussions and presentations of research clarified the costs and benefits of various drug disposal approaches that had been tried, and highlighted some of the program issues to be faced by the Maine program. These efforts ultimately stimulated the passage by State Legislation of Public Law 2003, Chapter 679, which formed the Maine Unused Pharmaceutical Disposal Program, and created the Maine Drug Return Implementation Group. This work group came to consensus that a mail-back approach would work best in Maine.

Meeting the Challenges of a Rural and Aging State

Maine ranks 38th in population density nationwide with fewer than 10 residents per square mile in over half of the state. This poses challenges to distribution and collection methods as well as financial challenges. Maine also has the oldest population in the country with a median age of 41.2 years (United States Census, 2005). Needing to travel long distances to bring unused drugs to a collection site would have posed problems for a substantial number of Maine's elders. Using the U.S. Postal Service system solves that problem because virtually all of Maine's citizens have access to the mail.

Selecting an Environmentally Sound and Legally Secure System

In addition to the issues involved in securing and transporting drugs over long distances, there was controversy about the best way to dispose of them. Program leaders were aware of the research about the environmental hazards posed by drugs getting into the groundwater, either through flushing or solid waste disposal. Although the financial costs and impact on air quality were also certainly important factors, incineration was ultimately chosen as the method of disposal for the mailback program as it would minimize environmental impact. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures.

Incineration avoids the problems of direct contamination of water. The MDEA had been using this method to dispose of drugs from law enforcement seizures. The form of

incineration already in use by the MDEA was a controlled, high-heat process designed to convert waste to energy. (See Appendix 4E for a breakdown of other drug collection methods with their advantages and disadvantages.)

Political Will and Partnerships

Issues surrounding the collection and disposal of pharmaceuticals involve many professional, legal, and regulatory agencies. For this reason any proposed project should be founded upon an extensive network of professional and community partnerships. Development of these working relationships took several years prior to actual implementation of the Maine program and involved each of those acknowledged at the beginning of this handbook.

Key project partners within Maine included the Maine Benzodiazepine Study Group, the Maine Department of Environmental Protection, the Maine Drug Enforcement Agency, the Maine Office of Substance Abuse, the Maine Department of Health, the Maine Office of the Attorney General, the U.S. District Attorney for Maine, and the University of Maine Center on Aging. A technical expert advisory task force was formed that included members from each of these and a cadre of partnering organizations. The Community Advisory Group (explained in more detail later) provided a critical consumer perspective, including the perspectives of individuals involved “at the front line:” the project volunteers handling community education and marketing.

The Maine Department of Health and Human Services and the Maine Department of Environmental Protection both provided assistance with public education and outreach in Phase I and II, and a representative from each group acted as their organization’s liaison to the project.

A number of state and national specialists and associations also committed to the project. Both the Community Medical Foundation for Patient Safety and the National Council on Patient Information and Education agreed to enlist their staff to review instructions and informational materials to be distributed to distribution sites and mail-

back participants. Rite Aid Corporation, the nation's third largest drugstore chain and the largest on the east coast, formally committed to participation in the pilot project with their pharmacies serving as distribution site locations.

Researchers from the University of Maine Margaret Chase Smith Policy Center committed to project evaluation and to act as an outside advisor to the project on matters related to drug disposal.

In Maine, there has also been a key legislative component to coalition building. In 2003, the Maine Benzodiazepine Study Group and the Maine Drug Enforcement Agency convened a group of stakeholders from various sectors and professions including children's advocacy, environmental and medical organizations, and higher education research units. The Center on Aging at the University of Maine assumed the administrative coordination of the project. The group's focus was to create legislative solutions to the problem of diversion, misuse and abuse of prescription drug medications.

A legislative mandate, Public Law 2003, Chapter 679,¹⁶ created the Maine Unused Pharmaceutical Disposal Program and tasked the Maine Drug Enforcement Agency with the program's administration. The Maine Drug Return Implementation Group was also formed. This group was tasked with addressing postal regulations, methods and requirements for mailing, minimizing drug diversion and theft of mailed returns, providing public education, and encouraging the development of turn-in programs. This mandate encouraged the implementation group to seek outside funds. A grant proposal was made to the U.S. EPA Aging Initiative to pilot the program (findings and activities covered in this report).

In 2007, the Maine Legislature enacted Maine LD 411 "An Act to Establish a Pilot Program for the Return of Unused Prescription Drugs by Mail." This initiative provided

¹⁶ See http://www.mainelegislature.org/ros/LOM/LOM121st/15Pub651-700/Pub651-700-126.htm#P9390_1232537

an additional \$150,000 to the pilot which allows the program to continue for an additional two years beyond the initial EPA grant.

Partnering with Law Enforcement is a Key Component

Close partnership with the Maine Drug Enforcement Agency (MDEA) provided the critical involvement of law enforcement. By law, only law enforcement entities are permitted to receive and handle returned pharmaceutical drugs classified as Schedules II, III, and IV, which includes narcotic analgesics, sedatives, and stimulants.¹⁷ Their involvement is necessary to insure security, to prevent drug diversion, and because the law requires it. Because of the likelihood that controlled substances would be an important subset of the returned drugs, the MDEA agreed to oversee receipt of drugs returned via this program.

Maine's mail-back program also required partnership with the MDEA in order to facilitate use of the already-established incineration disposal method, as well as to actually transfer the returned drugs for incineration.

Selecting a Central Coordinating Agency

From this base, the University of Maine Center on Aging (CoA) took the leadership role in seeking funding for a pilot study from the U.S. Environmental Protection Agency's Aging Initiative. The Center on Aging has a number of characteristics that were advantageous for this role. First, as a department within the University, the Center is a qualified non-profit organization and therefore able to receive federal funding. The CoA has the institutional base to act as the fiscal and administrative agent for what was to become a highly visible and complex project. This includes qualified personnel, experience with community/academic/government partnerships, and accessible, centrally-located headquarters that can house meetings and coordinate communications.

¹⁷ DEA Schedule of Controlled Drugs, <http://www.justice.gov/dea/pubs/csa.html>

In addition, the CoA is well-known statewide and trusted by communities and elder networks. They have established communication vehicles (website, newsletter, on-going functions) to facilitate the education and marketing so essential for an innovative project. The social network qualifications of the CoA proved to be beneficial during all phases of the project.

Developing Organization Capacity

The following sections of this report provide some basic guidelines in developing organizational capacity to address the problem of unused pharmaceuticals. If you are just starting a program it is important to refine your organization's intentions and clarify how you wish to proceed. In other words, agreeing on a mission, goals, and objectives. This is a necessary step not only in focusing your organization's resources, but also a requirement in order to seek external funding.

Each organization will be different. For that reason, we begin each of the following three sections with basic instructions that can be applied broadly. We then use our program as a specific example.

Developing a Program Mission

This first step focuses on your organization's values with respect to the problem or set of problems confronting your community. The mission statement should express what you want your organization to be in relationship to that problem?

Sample Mission:

As an academic-community partnership concerned with the environmental risks posed by the accumulation of unused household pharmaceuticals, we work together enthusiastically to support and implement a successful mail-back program.

You might begin by constructing the following: “We are [*insert a phrase that describes who you are as a group*] who agree on the importance of [*insert value/values*] in addressing [*insert problem you want to solve*], we will [*insert what you have agreed to do about it*]. After you decide on these components, you can edit the statement to make it flow better, for example: *As an academic-community partnership concerned with the environmental risks posed by the accumulation of unused household pharmaceuticals, we work together enthusiastically to support and implement a successful mail-back program.*

Goals, Objectives and Outcomes

Deciding on goals, objectives, and outcomes will help your organization do more effective planning and implementation. Articulation of these program components is usually required by funding agencies. Check carefully with the agency funding announcements, however, because agencies may differ in exactly how they define these terms.

Goals are the general targets your program will aim for, usually phrased as some sort of societal improvement. Setting goals is similar to setting a navigation course by pointing your sights toward a star or a distant land mass. Goal statements can then be clarified by defining and discussing concepts and terms used in the goal statements.

In contrast, *objectives* are specific, observable accomplishments that demonstrate progress toward the program goals, or even define ultimate goal achievement. Objectives can be mid-range or long-range. They can function as benchmarks or

milestones, signals along the way that let you know your efforts are successful as you move toward a goal. Or, long term objectives can be used to operationalize success in arriving at the program goal.

Objectives should be indicators that can be agreed upon, even by an observer or evaluator outside your organization. Objectives are useful for planning; they constitute the day-to-day things the organization must actually mobilize itself to do. They should be phrased in such a way that an administrator can use them in order to make decisions about how to direct resources and personnel.

Maine's Goals and Objectives

Maine's Goals

1. To devise, implement and evaluate a mail-back model
2. To test effectiveness of an educational campaign about risks of improper storage and disposal
3. Develop a framework for a national model and ensure replicability

The goals for a prescription drug return program in Maine, were two-fold: 1) to devise, implement and evaluate a mail-back plan to remove unused and unwanted medications, both prescription and over-the-counter, from residences and dispose of them in compliance

with applicable state and federal laws and sound environmental practices, and 2) to test the effectiveness of an educational campaign about the hazards to life, health, and the environment posed by improper storage and disposal of unwanted medications. A cost-effective model for the disposal of unwanted medication would be created and implemented, and an educational campaign would be instituted in each of Maine's 16 counties. Further, the project would address potential barriers to participation due to age, infirmity, rural locale, and other challenges.

Maine developed a list of 15 milestones and completion dates, which functioned in effect as intermediate program objectives. These included first a model development phase: (1) develop consolidation, transportation, and incineration protocols; (2) contract with incineration facilities and transportation vendors; (3) commence meetings of technical advisor task force; (4) secure network of 75 mailer distribution points (pharmacies); (5) engage community advisory board and commence meetings; (6) design and produce mailers, mailer survey, training materials for distribution site educators, and instructions for pharmacies and the public; (7) create web site and

Nuts & Bolts

Mission

Develop a program mission that expresses in simple terms what you want your organization to be.

Goals

Decide on program goals that express what you want your program to aim for in its work overall.

Objectives

Define medium-term and longer-term objectives, that is, clear benchmarks that need to be accomplished along the way in order to demonstrate you are achieving your goals.

Outcomes

Describe the measureable outcomes that will result if you have met your goals.

establish a toll-free helpline and helpline training materials; (8) engage and train distribution site educators; (9) develop public education campaign content and dissemination plan.

The implementation included a Phase I to pilot the program components, specifically: (1) launch Phase I education campaign; (2) distribute informational materials and provide training for pharmacists, staff, and individuals acquiring mailers; (3) collect, inventory, and destroy returned products from Phase I locations in compliance with applicable state and federal laws and sound environmental practices statewide; and (4) evaluate Phase I and refine for Phase II. Phase I program components were implemented and designed to specifically target older adults and caregivers.

Objective milestones for Phase II included: (1) distribute informational materials and provide

training for pharmacists, staff, and individuals acquiring mailers for Phase II; (2) collect, inventory and destroy returned products; (3) generate, analyze and report on survey and inventory data in a manner that allows physicians, pharmacists, insurance companies, patients, and others to modify behaviors to minimize unused medications;

Maine's Long Term Program Objectives

1. Conduct a statewide educational campaign on proper use and disposal
2. Calculate weight, type, and hazardous characteristics of returned medication
3. Calculate the cost of the mail-back program model

(4) evaluate need for Phase III (and institute as necessary); (5) conduct final evaluation; and (6) publish best practices handbook. It is important to note that Phase II expanded the program exposure to population groups beyond older adults.

Maine's long term program objectives included: 1) calculating the weight, type and hazardous characteristics of returned medications by actual pill count and drug classification; 2) calculating the cost of the mail-back program as a model for future use nationally, by other organizations and states; and 3) offering a statewide education campaign targeted toward the proper use and disposal of prescription drugs with an initial focus on citizens 65 and older.

Projected outcomes included: 1) understanding the practicality and costs associated with a mail back medication return program; 2) information on the best methods to educate older adults concerning the hazards of unused medications and improper disposal; 3) reduction in the amount of medications available for improper disposal, diversion or poisoning; and 4) heightened awareness by the public-at-large and older adults in particular that could lead to a reduction in accidental deaths, human and animal poisonings, and suicides caused by unused medications.

Maine's Expected Outcomes

1. An understanding of the model's practicality and costs
2. Information on best methods to educate older adults about hazards of unused and improperly disposed medications
3. A reduction in the medications in Maine available for improper disposal, diversion or poisoning
4. Heightened public awareness, especially in older adults, of the risks caused by accumulated or improperly disposed medications

THE BASICS OF THE PROGRAM

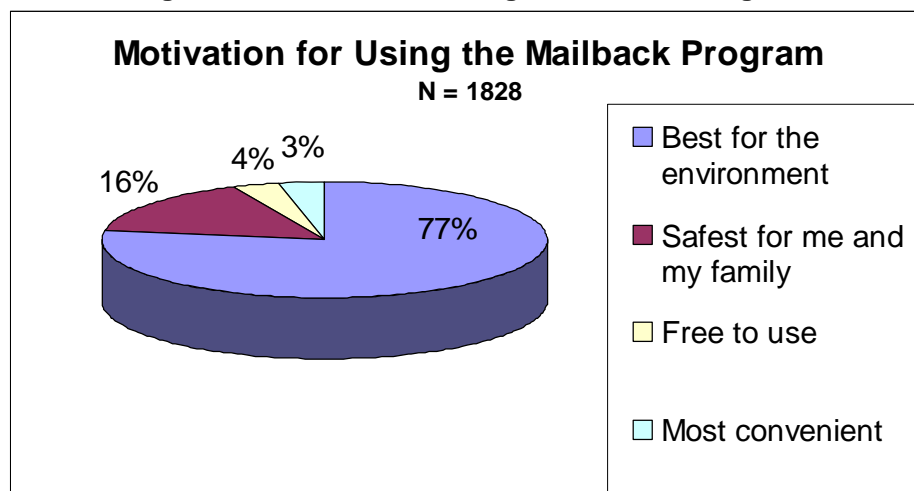
Why Maine Mailback Participants Use the Program

Findings from program participant surveys from the Maine SMDME program itemized multiple reasons for drug accumulation in their homes, including:

- Medicine belonged to a deceased family member (19.6%)
- A physician told the patient to stop taking the medication or gave the patient a new prescription (27.3%)
- The person had a negative reaction or allergy to the medicine (11.9%)
- The person felt better or no longer needed the medicine (18%)

Participants also noted multiple reasons for removing the drugs from their homes, including concerns for the environment, drug compliance, drug safety, as well as for preventing drug diversion. Some noted they did not want anyone else to use the medicine. Some were concerned about the potential poisoning dangers to children, or the risks of drug abuse diversion. Often the medicine was expired or outdated and no longer useful. In some cases this adds to their potential for misuse or harm.

Figure 1. Motivation for Using the Mailback Program



Nearly half (46%) of those surveyed reported that, in the absence of a take back program, they would have flushed drugs down the toilet. Another one third (37%) would

have dumped left over prescriptions into their trash. These disposal solutions can pose environmental risks. Overwhelmingly, 77% of program survey respondents cited participation because, “it’s best for the environment.”

Overwhelmingly, 77% of program survey respondents cited participation because, “it’s best for the environment.”

Refining the Concept: The Mail-Back Model

There are five primary models for drug take-back programs. The first, a pharmacy-based take back program, which is considered to be a controversial approach nationally. Because returned medications often include Schedules II, III, and IV drugs, which have a higher abuse potential, the DEA regulations require that they be received and transported by law enforcement personnel.

In-person event-driven take back programs, the second model, are coordinated locally (community-by-community) and would take the commitment of multiple police departments and multiple law enforcement agencies to enact a statewide program. Such events are offered sporadically and rely on local law enforcement to shoulder the time commitment and costs associated with take back programming.

The third and fourth models, police department drop-off and pick-up, are emerging models that have been developed through local community policing efforts. Both models are not yet widely available but continue to grow in popularity in local communities.

The fifth model, a statewide mail-back prescription return program, was most appropriate for Maine. It allows drugs to be returned directly to one agency, which reduces coordination costs. In Maine, the Maine Drug Enforcement Agency (MDEA) has statewide jurisdiction and had been involved in concept development. It was therefore the most appropriate for piloting in Maine. The statewide mail-back model

offers a centralized coordination component, adds an element of confidentiality and anonymity not found with in-person take back programs, and is the least burdensome of all models in terms of consumer participation (see Appendix 4E for a comprehensive review of various models).

The statewide mail-back model offers centralized coordination..., adds ...confidentiality..., and is the least burdensome of all models in terms of consumer participation.



Figure 2. Center on Aging staff member orients a participating pharmacist to the program

Tasks Leading Up to the Actual Mailback

Before a mailback can begin, there are a number of preliminary tasks that must be accomplished. In Maine, this included the following (see Appendix 3 for complete timeline):

- Create consolidation, transportation, and incineration protocols
- Contract with incineration facilities and transportation contractors
- Commence meetings of technical advisory task force
- Secure network of distribution points (pharmacies, community sites, etc.) to which mailers are distributed in both phases

- Engage community advisory board members
- Commence meetings of community advisory board
- Design and create mailers and accompanying survey, training materials for Distribution Site Educators and instructions for pharmacies and public

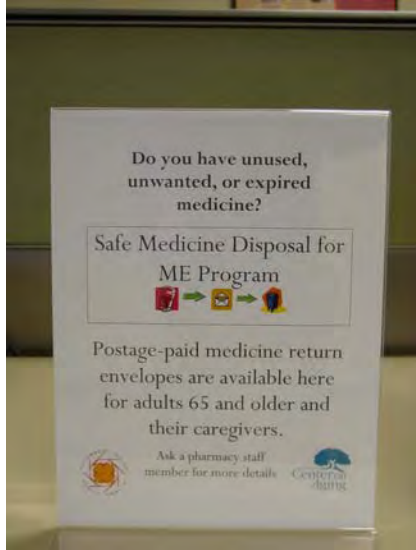


Figure 3. Each pharmacy receives a program sign to market the availability of envelopes

- Create web site, establish 800 number call center and create related training materials and protocols
- Engage and train Distribution Site Educators
- Develop education campaign content and communication dissemination plan
- Launch Phase I education campaign
- Distribute informational materials for pharmacists, staff, and individuals acquiring mailers for Phase I; provide training

The Bottom Line: Costs and Funding

Below is the actual phase I and II budget for the Maine program. As noted, the per-envelope cost in the initial years of the program is significant given the staff time and effort needed to create a novel program. Additionally, the value of donated time from pharmacists and pharmacy tech staff totaled approximately \$800 for each inventory event toward the end of the project period. The time and effort contributed by Community Educator volunteers was calculated to be \$20.25/hour as estimated by the Independent Sector.¹⁸

¹⁸ www.independentsector.org

| Phase I and II Actual Program Costs | |
|--|--------------------|
| (9,400 envelopes, 42% return rate) | |
| Budget Line | Actual Cost |
| Envelopes (including freight); supplies and materials | \$6,214.38 |
| Assembly and printing (assumes color printing and survey printing and assembly) | \$9,358.62 |
| Postage including PO Box permit | \$11,310.22 |
| Disposal for both controlled and non-controlled drugs (2,123 pounds non-controlled and 250 lbs controlled) | \$7,111.00 |
| DEA staff costs, data analysis consultants, research consultants | \$21,402.13 |
| Website and Phone costs (User support) | \$4,237.53 |
| Travel for cataloging/research activities/program administration | \$4,000.00 |
| Staff time-program administration | \$50,002.12 |
| Subtotal | \$113,636.00 |
| Indirect Costs: Facilities, grant and contract administration, etc. | \$36,364.00 |
| Total cost: | \$150,000.00 |
| Per unit cost: | \$15.96 |
| In-kind provided to the project in Phases I and II | \$26,607.13 |
| Per unit cost factoring both actual costs and in-kind provided | \$18.79 |
| In-kind detail: 9,000 mailers donated by Polyair Manufacturing: \$2,394.63; Time and effort donated by Principal Investigator: \$11,130; Pharmacist and pharmacy staff donated time: \$6,400; Community Educator volunteers (330 hours x \$20.25 per hour value): \$6,682.50 | |

Now that piloting has been completed for the program, the administrative costs for the program have been reduced considerably. Below is the currently two-year operational budget for the mailback program which includes enough funding to distribute and process 20,000 mailback envelopes from across the state.

Phase III Two-Year Budget

Base of 20,000 envelopes, 30% return rate assumption

| | |
|---|---------------|
| Envelopes (including freight) | \$6,200 |
| Assembly and printing (assumes color printing and survey printing and assembly) | \$12,000 |
| Postage (\$2.50 average per returned envelope) | \$15,150 |
| Postage Fees (permit and PO Box for one year) | \$1,850 |
| Disposal | \$16,000 |
| DEA staff costs | \$10,200 |
| Cataloging, data entry, data cleaning, reporting (pharmacist time, data entry staffing) | \$12,000 |
| General supplies | \$3,800 |
| Website and phone costs (User support) | \$2,805 |
| Travel for cataloging/research activities/program administration | \$3,000 |
| Staff time-program administration (40%FTE) | \$47,506 |
| Volunteers (training, travel, support costs) | \$2,000 |
| Subtotal | \$132,511 |
| Indirect costs (13.4%) charged on all direct costs except volunteer/participant support | \$17,489 |
| Total cost: | \$150,000 |
| Per unit cost: | \$7.50 |

* budget assumes 30% return rate after Phases I & II

Implementation Structure

The Safe Medicine Disposal for ME mail-back model was conceived in two phases and has since moved into a third phase:

Phase I Overview: In this pilot program, 1,800 postage-paid, padded mailers were made available to consumers at 11 pre-selected pharmacies in four Maine counties (see Figure 4). Counties were selected for their geographic disparity, access to rural and urban communities, and demographic characteristics of residents (age, socioeconomics, education, culture, lifestyle, etc.). This initial phase allowed staff to monitor the program, pilot protocols, and revise as needed before Phase II implementation went statewide. Phase I did not include marketing strategies or a public education component, and there was limited press coverage of the program. Only persons aged 65 or older and their caregivers were encouraged to participate.

Phase II Overview: Safe Medicine Disposal for ME went statewide in Phase II with 7,600 mailers available in all 16 Maine counties (see Figure 4). Initial envelope distributions to sites during this phase were based on county population size. Pharmacies continued to be the primary point of distribution for program envelopes, although site selection expanded to include health agencies, doctors' offices, social

service programs, and Area Agencies on Aging. This phase included a public education component with extensive, targeted marketing urging individuals into distribution centers for the purpose of picking up and using return mailers. All age groups and caregivers were eligible to participate in the program.

Phase III Overview: During Phase III the program was expanded to additional sites within the state's 16 counties (see Figure 5). The program remains open to participants of all ages.

Safe Medicine Disposal for ME

The Process At a Glance

- Distribution sites are solicited and trained (Appendix Group 5 includes Distribution Site materials)
- Volunteer staff are trained (Appendix Groups 6 includes Helpline and Volunteer materials)
- Brochures and other educational materials are created, and volunteer staff begin presentations in communities (Appendix Group 8 includes Consumer Education Items)
- Volunteer staff distribute postage-paid, padded return envelopes to pharmacies and other health and social service agencies across the state at no cost. (Appendix Group 7 includes information on Mailback Materials).
- Pharmacy and agency staff give an envelope which includes an instruction packet (Appendix 7A) and a consumer survey (Appendix 7C) to any interested participant.
 - Participants are asked to use a black permanent marker to write over the name of the person for whom the prescription was written. They are asked not to write over the name of the medicine or the dose.
 - Liquids or creams are to be wrapped in a paper towel and placed in a Ziploc bag.
 - Sealed medicine bottles along with any Ziploc bags of liquid are to be put into the padded self-addressed return envelope and sealed.
- Participants return the completed survey and drugs to the Maine Drug Enforcement Agency (MDEA) using the postage-paid return envelope provided.
- Participants are asked to write down the envelope code written on the corner of the medicine envelope and call the program help line to leave a message with the envelope code and the date it was mailed.
- Envelopes are received and held by the U.S. postal service.
- Drug enforcement agency officials pick up collected envelopes periodically and take to a secure central location where they are logged and catalogued. Questionnaires are returned to the Center on Aging for analysis at the time of cataloging.
- Medicine is destroyed via incineration.

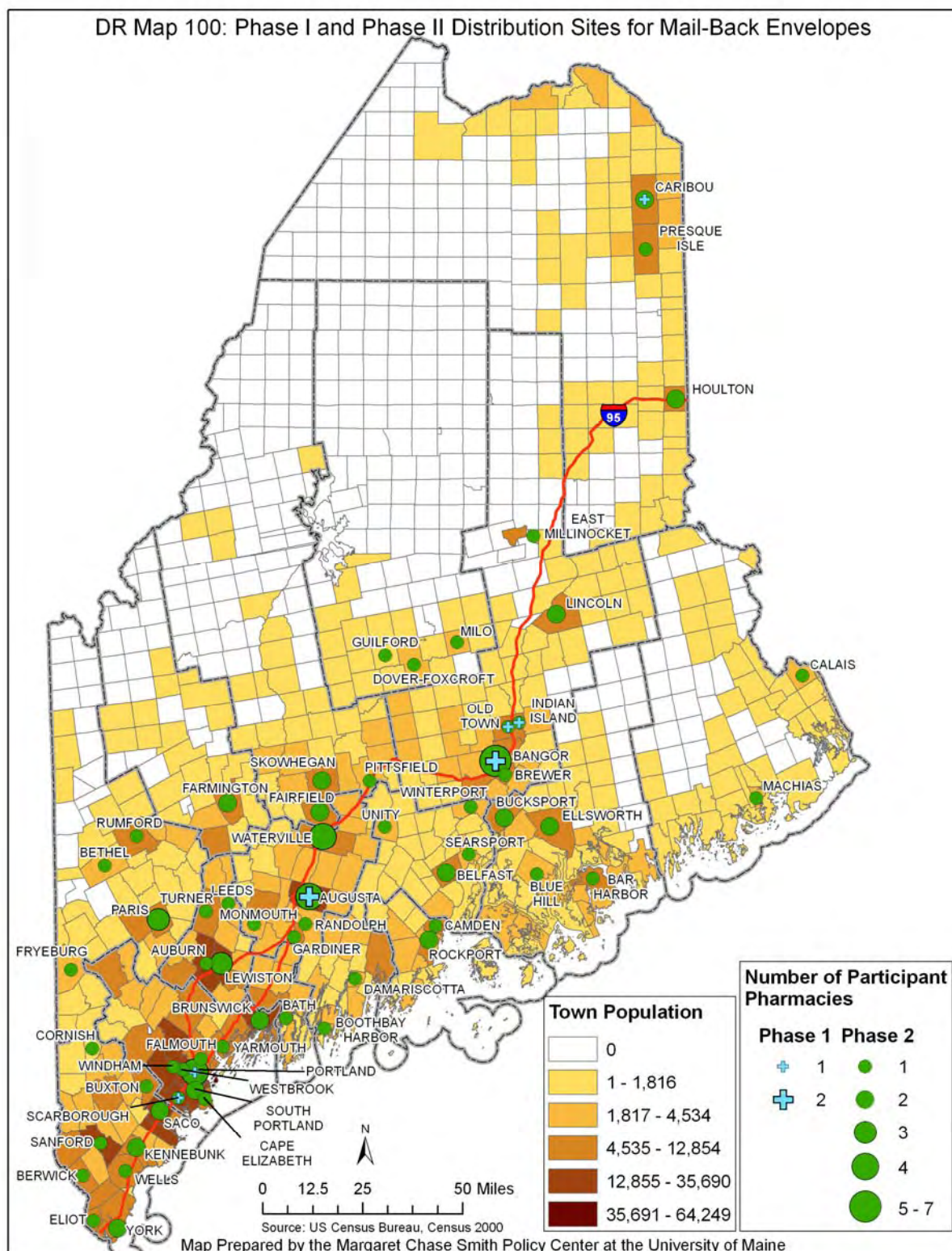


Figure 4. Map of Phase I and Phase II distribution locations showing township population density

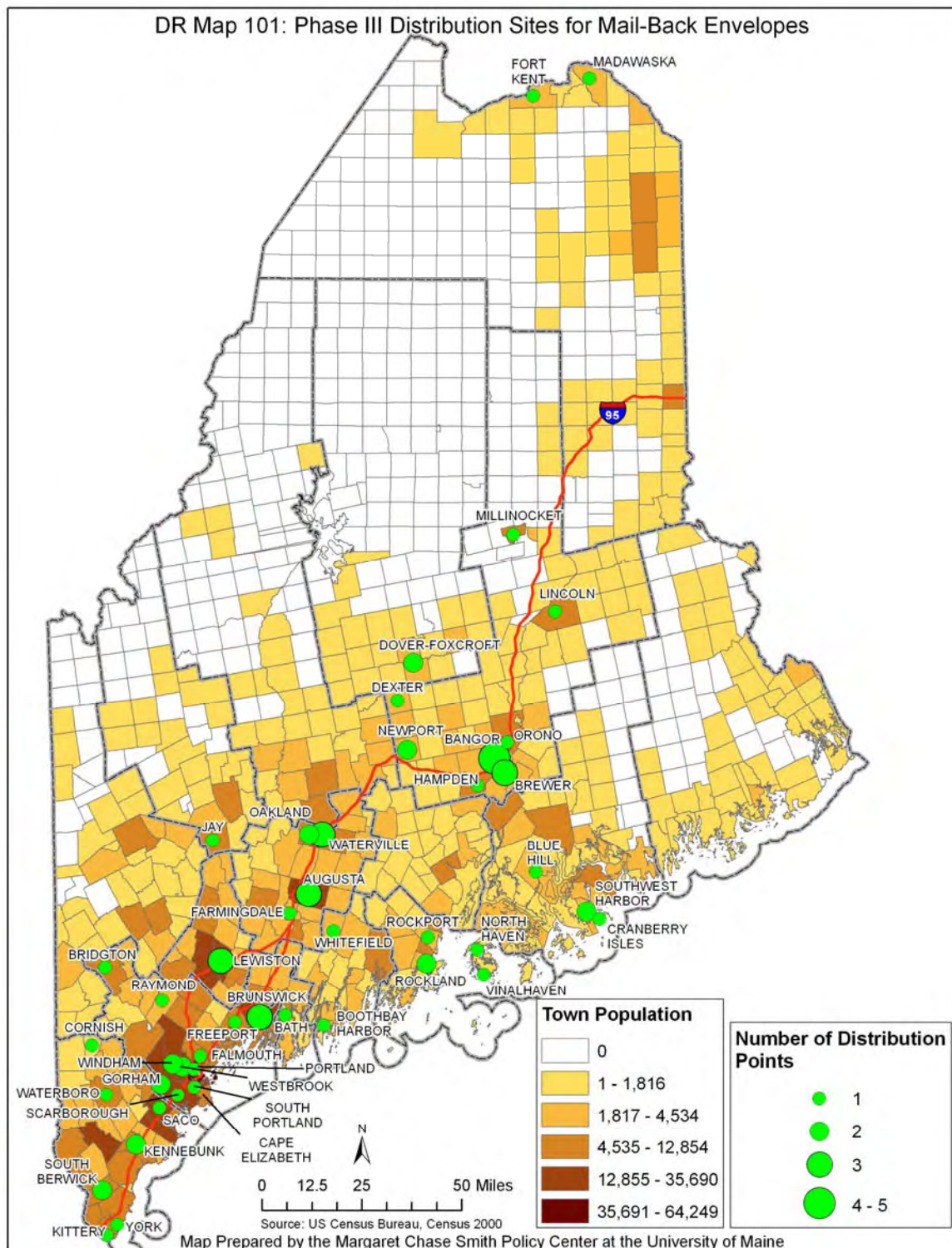


Figure 5. Map of Phase III distribution locations showing township population density

The Mailer

Center on Aging staff tested a variety of padded mailers. There are many to choose from depending on project budget constraints, and selecting the size of a chosen mailer will have cost implications. Minimally, mailers need to have a tamper-evident seal and should be nondescript--not easily identifiable as containing drugs. Mailers chosen for Safe Medicine Disposal for ME are 7.25 x 12 inches and can hold four different bottles of prescriptions and six to eight ounces of drugs, although it has held up to a pound of drugs. The specific mailer chosen was the XPak mailer manufactured by Polyair.¹⁹

Figure 6. Stack of mailback envelopes



In Maine, each mailer is accompanied by a questionnaire along with an instruction booklet on how to properly prepare and mail the envelope (see Appendix Group 7). The questionnaire is designed to assess the nature of the returned product(s) as well as reasons for their return. Information collected includes basic demographic data, source of contents, patient

identification of contents and reasons for surplus.

During Phases I & II, 9,400 envelopes were distributed and 3,926 envelopes were returned generating 2,373 pounds of unused and unwanted medicines. As reported by the Community Medical Foundation for Patient Safety, almost 17% of medications returned through the Maine Program were found to be controlled drugs (see “What We Have Discovered” section of this report). Older medications have not been uncommon; some of the prescriptions returned were noted to be twenty or more years old. It is also

¹⁹ For more information visit www.xpak.com

estimated that several of the envelopes returned to date have contained enough unused narcotics to net thousands of dollars if sold on the street.

The Mail System & The USPS

In Maine, an “operational test agreement” was formed between the U.S. Postal Service and the Maine Drug Enforcement Agency – the first of its kind. Operational test agreements are traditionally crafted so the postal service can test out novel options.

Figure 7. Phase I envelope shipments to distribution sites were prepared in-house at the Center on Aging



These agreements are time limited contracts, and each state will need to pursue an agreement within their own state. Because there had been no previous template for this sort of agreement, the process in Maine took more than a year to finalize. Important decisions to be made include the type of mailer to be used, how to educate the public about the program, and how to ensure the safe delivery of envelopes to

the receiving drug enforcement agency. A copy of the Memo of Understanding between the U.S. Postal Service and the Maine Drug Enforcement Agency is provided in Appendix 4D.



Figure 8. CoA staff member prepares Phase I envelope shipment to pharmacies

Figure 9. Phase I boxes ready for shipment to program sites



When The Mailers Come In, Then What?

Using a double verification process, MDEA law enforcement personnel count and collect returned mailers from the Post Office on a regularly scheduled basis and take them directly to a secure consolidation facility. The audit process involves a repeat count of the number of packages received and verification of accounting logs conducted by the UMaine Center on Aging. Throughout the process the MDEA maintains continuous, unbroken custody of the returned medicine.

Cataloging of returned drugs was done under law enforcement supervision by volunteer project pharmacists and pharmacy students. As participation has increased over time,

the program has moved from cataloging 100% of returns to a 25% random sample to a 20% random sampling procedure. Using a sampling method was found to be both cost effective and yielded a data sample that was statistically representative of the full inventory data set. For the envelopes that do not receive a full inventory, all non-controlled drugs are sorted for disposal, and all controlled drugs are fully inventoried.

During the cataloging, drugs were sorted according to whether they were controlled drugs or not and further into controlled hazardous or controlled non-hazardous categories.²⁰ This sorting method facilitates appropriate disposal and therefore helps control disposal costs.



Figure 10. Volunteer pharmacists and pharmacy staff inventory returned medicine



Figure 11. Boxes of inventoried medicine



Figure 12. Drugs are occasionally returned mixed together and without their original container.

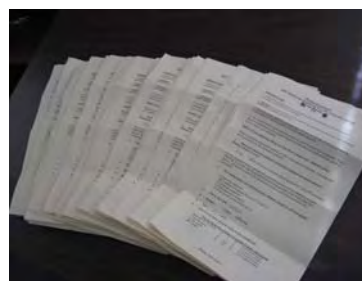


Figure 13. Returned consumer surveys collected at a drug inventory event.

²⁰ Very few drugs have been found to be both controlled and hazardous.

Collection, Inventory and Disposal Requirements

In compliance with the Maine Drug Enforcement Agency and the Department of Environmental Protection, drug collection, inventory and disposal included the following elements:

- 1) Double verification of returns
- 2) One secure collection and consolidation facility
- 3) Repeat count of the number of packages that have been received
- 4) Proper disposal of all drugs collected
- 5) Continuous, unbroken custody by law enforcement from receipt to disposal

Disposal Mechanics

Various methods of disposal, good and bad, for collected prescription drugs have been traditionally used by consumers and facilities including: flushing down the toilet, throwing medication out in the trash, burying in a landfill, burning, or mixing substances with kitty litter and used coffee grounds to make results undesirable. In Maine, drug disposal options were to be considered if they satisfied the requirements and standards of the Department of Environmental Protection and the Maine Drug Enforcement Agency. Maine DEP has classified drug returns as hazardous waste, while other states may classify drugs differently. All non-controlled drugs collected by the mailback were incinerated as hazardous waste. All controlled drugs were disposed of through incineration with a witness from the Maine Drug Enforcement Agency to certify that the drugs were in fact destroyed.

Volunteer Workforce: Elder Involvement is a Critical Component

It cannot be stressed enough how important volunteers, in particular older adult volunteers, are to the program. The first two external groups to be developed, the Community Advisory Board and the Distribution Site Educators, are outlined below. Members were recruited by print, broadcast, and word-of-mouth.



Figure 14. Community Educator volunteer orients community pharmacist to the mailback program

In Phase I, the 15-member Community Advisory Board was comprised of volunteers age 65 and older recruited from the Retired Senior Volunteer Program (RSVP), Maine Area Agencies on Aging, and other older adult organizations and associations from urban, rural, and suburban areas in each county represented in the pilot project. Board members reflected the population's diversity by gender, socioeconomic status, and education. In the early stages,

Community Advisory Board members attended monthly meetings and acted as a sounding board for the project, in part to review brochures, instruction booklets, and marketing strategies for applicability to an elder community. The board has also provided valuable insight into the rural Maine communities represented by individual members.

Volunteer Distribution Site Educators included community members from around the state and Community Advisory Board members. In Phase I, their purpose was to deliver mailers and materials and to educate distribution site pharmacists and staff about the program process. This role was discontinued for a variety of reasons, one being that pharmacies were often too busy to meet with Educators and orientation materials as designed were fairly self-explanatory. Beginning in Phase II, Educators organized and attended meetings at local Chambers of Commerce, Kiwanis clubs, senior centers, and nursing homes to educate members of their own communities about

the mail-back program. Presentations included a PowerPoint slideshow, a presentation quiz, and handouts (Appendix Group 8).

Evaluation data for community education sessions were gathered via a post-session survey tool. One hundred and fifty-one surveys (151) from education session participants were gathered and analyzed. Participants in community outreach and education presentations range in age from 20 to over 80 years old. The majority of participants were within the 60-80+ age range. Eighty-seven percent of participants are female and 13% are male. Ninety-four percent (94%) of participants had never participated in a community drug disposal event prior to attending the education session. This indicates that the presentation is often touching upon new topics and disposal issues to which participants had not yet been exposed. Ninety-seven percent (97%) rated the overall drug disposal presentation as “good” or “excellent.” The average exam score on post-presentation evaluations was 95/100 indicating that the training has a high level of impact on knowledge. A sampling of comments from education session participants:

- Very helpful/informative
- This information is very important!
- Hank (CAB volunteer) has a wonderful way of presenting and relating to people. His talk was very well received by folks at the Knox county TRIAD meeting
- Very necessary information! Well done!
- Lynn (CAB volunteer) was great with the women attending!
- Well done! / Good job!
- Important information-much needed in our community!
- It is my understanding when people take meds, then urinate, the meds end up in the sanitation systems and cause gender confusion.
- Great! Entertaining and informative

An additional avenue for volunteering with the Maine program was the use of volunteer pharmacists from distribution sites who were recruited to catalogue returned drugs.

Pharmacy tech staff and students volunteered their time under supervision of the pharmacists to assist in data collection. This assistance was provided by Miller Drug, a local community pharmacy, volunteer licensed pharmacists, along with faculty and staff from Husson University School of Pharmacy, and the University of New England College of Pharmacy.

Communication Systems

The mailback program utilized several project-specific communication vehicles, two-way communication “channels,” to stay in touch with a primary network of advisors and to interact with the public: meetings, a consumer website, and a helpline. In addition, the Center’s newsletter *Silverwire* often contained project updates. Two-way communication allowed the project to be responsive to unanticipated problems.

Regular meetings of both the Technical Advisory Board and the Community Advisory Board offered an opportunity for the project staff to share successes and problem-solve, and to receive and send feedback to/from the public and other concerned stakeholders.

The project website (www.safemeddisposal.com) provided a “one-stop-shopping” solution for people who wanted to know about the project or check policy changes. The website was heavily used by both local and out-of-state persons interested in the project. In addition, website visitors were able to send an email inquiry to project staff. During the last most recent reporting period, for example, project staff received approximately one email a day during the work week. E-mail was used most by caregivers and professionals. Caregiver requests were usually for an envelope to be mailed to them because a nearby site location was not available via the program. Professional inquiries tended to come from pharmacies and other sites interested in participating in the program. Additional requests that came in by e-mail were from other states looking for information on the program for replication purposes. A sampling of states requesting information about the program model include: Oregon, Washington, D.C.; New York; California; Florida; New Hampshire; and Washington. As an example

of the national impact of the pilot, please see the U.S. Postal Service press release in appendix group 4.

The helpline, which was staffed by student interns, proved to be a very critical component of the program communication system. This phone number was liberally circulated to pharmacies and community sites, and was found on virtually all program informational material. During a recent three-month reporting period, the project received 727 calls, an average of more than 10 a day during the workweek. Two thousand seven hundred and seventy-seven (2,777) calls were received over the 2.5 year reporting period. Many of these have been from individuals calling the program to alert staff that they were mailing an envelope. Additional sources of inquiries included pharmacies, healthcare, and community sites that are interested in becoming established distribution sites. Thus the helpline functions in recruitment as well as information exchange.

Communication “Channels”

1. Advisory board meetings
2. Project website
3. Project helpline
4. Agency newsletter
5. Media releases
6. Public presentations
7. Evaluation forms at community education sessions
8. Survey instruments inside mailers

Feedback Loops: Tracking and Evaluation

Feedback loops existed as a function of the evaluation forms distributed at each community education event. These events were usually staffed by volunteer community educators trained for the project. In addition, each mailer contained a short survey, which was designed to learn about the demographic profile of the participant, the reasons for participating, the sources of the drugs, and the reason they had accumulated.

But beyond these basic tracking mechanisms, a thoughtful program evaluation should be a critical component of any publicly funded effort. Without well-designed evaluation methods, programs do not have systematic ways to measure success, to improve systems, or (minimally) to programmatically account for their expenditure of public monies.

Program evaluations should track and account for whether the program meets its benchmarks along the way as outlined in the workplan (formative evaluation). These feedback mechanisms should be built into the project's internal information systems. In addition, program evaluations should assess whether the project met its overall goals, as indicated by measurable outcomes (summative evaluation). Programs often find it challenging to identify outcome measures that clearly reflect the efforts of the project in achieving its goals.

If they are to be used for quality improvement, outcome measures should ideally be selected to reflect processes over which the project has some control and which move it toward its selected goals. In other words, depending on the outcomes, one should be able to actively “tweak” the systems, if necessary, in order to get an improved result. The link between program effort and its outcome should be clear (visible) and measurable (ideally by an objective observer) in either qualitative or quantitative terms. It is only when both the process and outcomes are documented that the program has the potential to become “evidence-based,” evidence being the best source of informed policy.

Public Relations and Marketing

A unique education campaign was implemented for Maine in two phases. In Phase I, education provided by the program was done via the program website and program brochures and tipsheets. The purpose of these materials was to enlighten the public on the hazards to life and health posed by unused drugs. The explicit message and goal was to reduce/eliminate unused medications in circulation and improper disposal

because of the significant potential for human and environmental harm as well as to advance public knowledge about protecting, sustaining and restoring the environment. The Phase II campaign built upon the messages established in Phase I and incorporated a new message encouraging the public to visit distribution sites statewide to acquire and use mailers. Phase II education efforts were rolled out locally via multiple media channels and local in-person presentations by volunteers in a more extensive and purposeful fashion than in Phase I to measure the impact that such education would have on the use of the program.

Because of the higher rate of pharmaceutical usage among older adults and the higher risk of accidental misuse and/or overdose within this population, special emphasis was placed on crafting cohort-specific messages during both phases and utilizing communication channels targeting specific user groups.

Effective Use of the Media

Communication with the public via print, digital, and broadcast media constitutes an essential part of program planning (see Appendix Group 9). The University of Maine's Public Affairs department was routinely used as a vehicle to develop and circulate press releases. Staff generated program drafts of press releases and welcomed input from those who specialize in this type of communication. Relationships between programs and such specialists, including public information officers, journalists, news anchors, and other writers can be very helpful in designing interesting and appropriate material that targets particular readerships/audiences. They used material the program generates and augmented it for their particular purpose, sometimes with an interview of program staff or program volunteers.

Program staff encouraged volunteers and partner organizations to “get the word out” by providing basic informational materials so that there was a uniform source for basic facts and concepts while leaving room for each outlet to augment the material as appropriate. For example, a media template was provided to local papers and community contacts that could be used as a backdrop for a story about a local person,

group, or educational event. An example of the template is included in Appendix Group 9.

Material generated for local community education, such as PowerPoint presentations, was made accessible for interested and involved citizens to use. This accessibility is important in increasing the speed at which a new idea (the drug mailback concept) can reach a large number of people. In this way, media and publicity efforts dovetailed with the heavy use of volunteers for outreach, training, and communication.

The Value of Research

Whether or not you plan to do any formal research as a part of your mailback program, research findings will nevertheless flow from your efforts. The experience gained by conceiving, planning, and implementing this program will include conclusions based on information. It will probably also include evaluation findings about how you reached your objectives, how well certain efforts worked, and ways your program is similar or different than others like ours. We strongly recommend that, at a minimum, you take advantage of your experience by carefully documenting your plans, progress, and experience. Your documented findings will be of use in (1) educating others about your program, (2) building political support for future programs, (3) writing proposals to funding agencies to obtain funding, and (3) designing public policies in your region and nationally. Simply collecting weight or estimated dollar value of the drug returns collected provides very little precise data on which to formulate policy or useful insights on drug accumulation.

Some levels of research are limited by resources, but should be attempted if possible. In particular, cataloging the drugs returned requires secure settings and professional input from pharmacists and healthcare volunteers, as well as some research skills to analyze the results. Ideally, funding is allocated in your budget ahead of time for some research. Sometimes, as is the case for the Maine program, volunteers can boost your efforts. For example, local schools of pharmacy may be interested in using this as an educational experience for students. The program also partnered with the Community

Medical Foundation for Patient Safety in Texas, which is working to establish a national database of drug returns to assist in research design and data analysis.

Take-back programs are in their infancy, but growing fast. Because of their potential impact on environmental policy, healthcare policy, and public safety, it is very important that good data are developed describing their scope and impact. Knowledge about the amount of excess drugs collected in Maine has been informative in refining Maine Medicaid policy, for example, leading to limits for some drugs on how much can be prescribed (see Appendix 4F regarding the new 15-Day Rule). And the Maine state legislature, along with other states, is considering new product stewardship laws that would require pharmaceutical companies to cover the cost of drug disposal.

What We Have Discovered with Our Program Research

The short survey included with each mailback envelope yielded vast amounts of data on the demographic characteristics of participants, the reasons drugs had accumulated in their households, and reasons for participating in the program. Each envelope has a code number pre-printed on the front which allows for linking survey data directly to drug inventory data. Several databases are currently maintained by the program including: envelope tracking and distribution databases, a survey database, a database with community education session evaluations, drug inventory data, and helpline communication logs. These data are valuable indicators for future programs and helpful for designing program materials and community education.

As the program continued into Phase II, increasing demand by non-pharmacy organizations lead to the expansion of distribution channels to a wider range of distribution sites, including home health agencies, doctor's offices, social service programs, and Area Agencies on Aging. After examining returns patterns, a trend was noted that revealed that returns are directly related to the population size within the areas where sites are located. However, the rate of return for each site was not calculated. As such, site locations and distribution patterns for the program were modified to ensure that envelope stock is used in an efficient and appropriate manner.

Maine's program was targeted for elders initially, although program staff quickly anticipated that it made sense to expand to adults of all ages given the drug abuse and death trends within the state. However, it was discovered that starting with older, retired citizens was a very effective strategy to launch this new concept. First of all, they are likely to have more prescriptions and more likely to be willing and available to assist in the program as volunteers. The average age of program users in Phase I was found to be 70 years of age; once the program opened up to adults of all ages, the average age of program participants (those who return drugs using the envelopes) was found to be

Safe Medicine Disposal for ME Phases I & II Snapshot

- \$150,000 in funding provided by the U.S. EPA to pilot in Phases I & II
- 9,400 envelopes distributed
- 3,926 envelopes collected (42% return rate)
- Over 380,000 pills cataloged via the drug inventory process
- 2,074 surveys collected and analyzed
- 2,777 telephone calls answered via the program helpline
- 2,123 pounds of non-controlled drugs destroyed
- 250 pounds of controlled drugs destroyed
- Average weight of a returned envelope: 7 ounces
- Estimate Average wholesale price (AWP) of medicine collected: \$572,772.35 (US Dollars)*
- Value of donated envelopes by Polyair, donated time by Principal Investigator, pharmacist, student, and volunteer time donated to the program: \$26,607.13**

Percentage of individuals using trash or toilet to dispose of drugs prior to the program = 83% x 2,373 lbs of drugs = 1,970 lbs of drugs prevented from entering the water supply and landfills

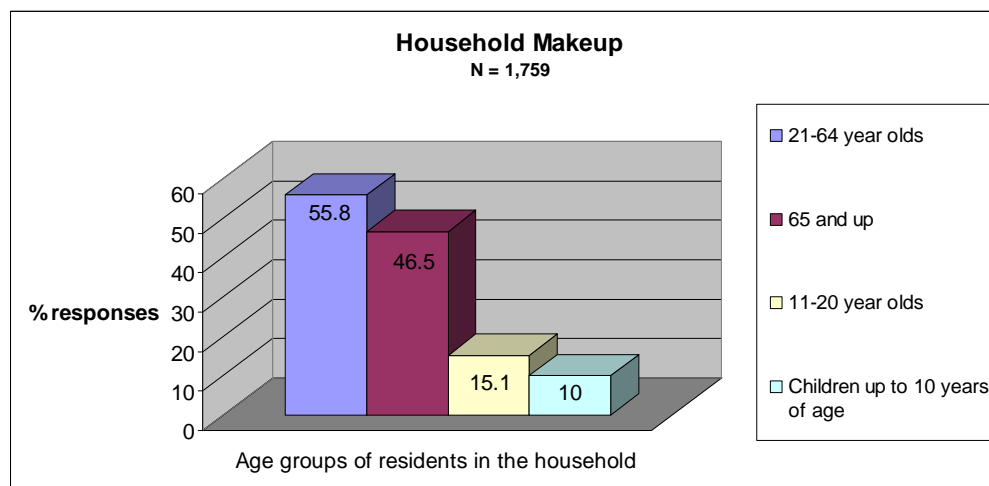
***Estimate provided by Community Medical Foundation for Patient Safety based on sampling. MAC, or Maximum Allowable Cost, was not calculated**

**** See "The Bottom Line" section of this report.**

59 years, with 65% of participants being female. Households participating in the mailback program were more likely to have adults rather than children living in the household. However, nearly one quarter of the participating households had a teenager

in the household or a child under the age of 10 years old. This information was tracked to measure the potential for preventing accidental poisonings or drug diversion.

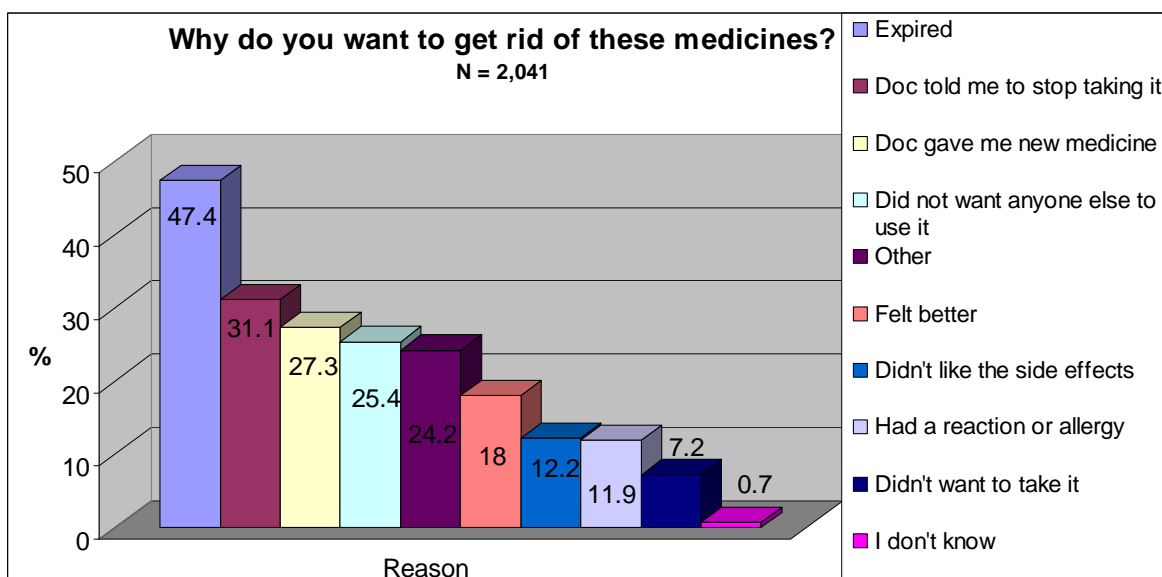
Figure 15. Household Makeup of Mailback Program Users



Participants indicated a number of reasons the drugs had accumulated in their household. The most frequent reason given was that the medicines were now expired or outdated.²¹ The second most common reason was that the doctor had told the patient to stop taking the medicine. Other reasons were that the doctor had given them a new prescription, that they had had a negative reaction or allergy to the medicine, or that the patient felt better or no longer needed the medicine. A substantial number of participants wanted to prevent anyone else from using the medicine. The open-response option for this question also yielded a considerable portion of respondents who were returning medicine for a deceased loved one. Based on these data, we began tracking the portion of respondents returning medicine for a deceased family member or friend. Most drugs returned via the program were obtained at a local pharmacy (84%) or by mail (14%).

²¹ Older medications were not uncommon. Some were prescriptions noted to be as many as 20 or more years old.

Figure 16. Reasons for Unused/Unwanted Medicine



Our survey findings show that keeping household medications organized and up-to-date can be an important and constant chore, not only for patients, but also for their caretakers. In fact, while 41% were returning medicine for themselves, thirty-five percent (35%) were returning medicine for a relative, and nearly 20% were returning medicine for a deceased friend or loved one²². The decision about what to dispose of can be complex as indicated by the fact that 16% of our respondents did not know what kind of medicine they were returning.

²² Many survey questions allowed the respondent to select more than one response option thus not all percentages within the charts provided will add up to 100%

Figure 17. Source of Medicine Returned

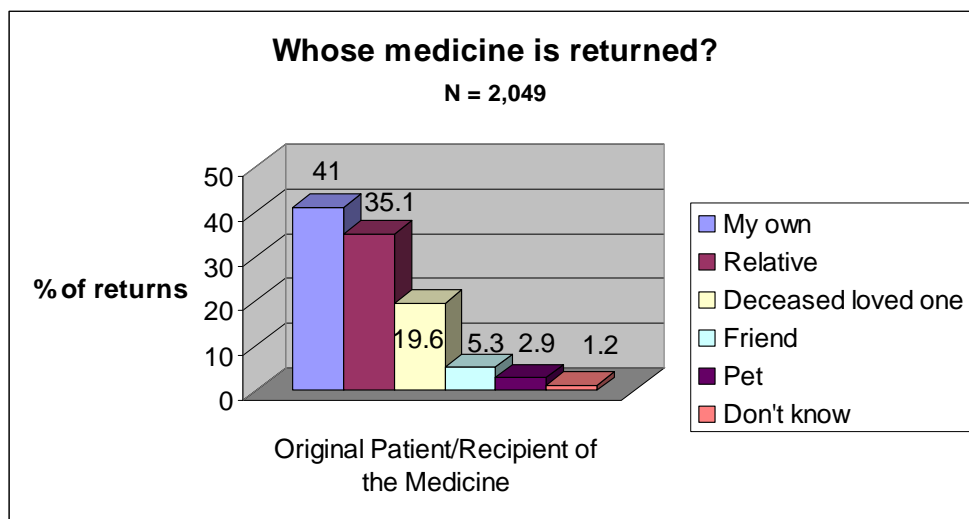
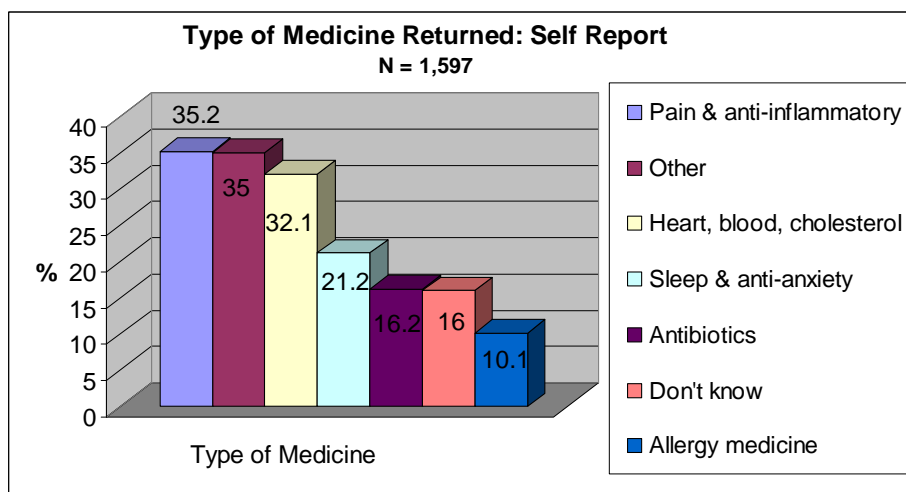


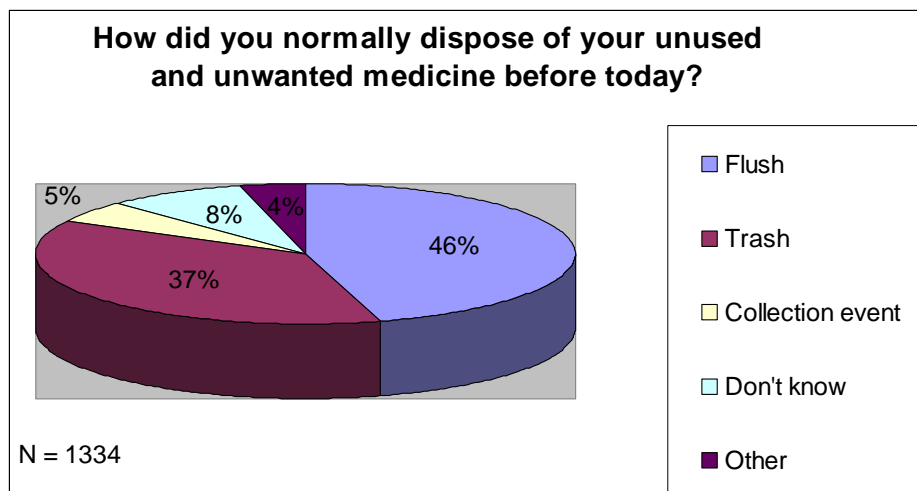
Figure 18. Type of Medicine Return: Self Report



Prior to this program, participants said that they usually flushed medications down the toilet (46%) or placed them in the household trash (37%). A smaller number said they had attended community drug collection events (5%).

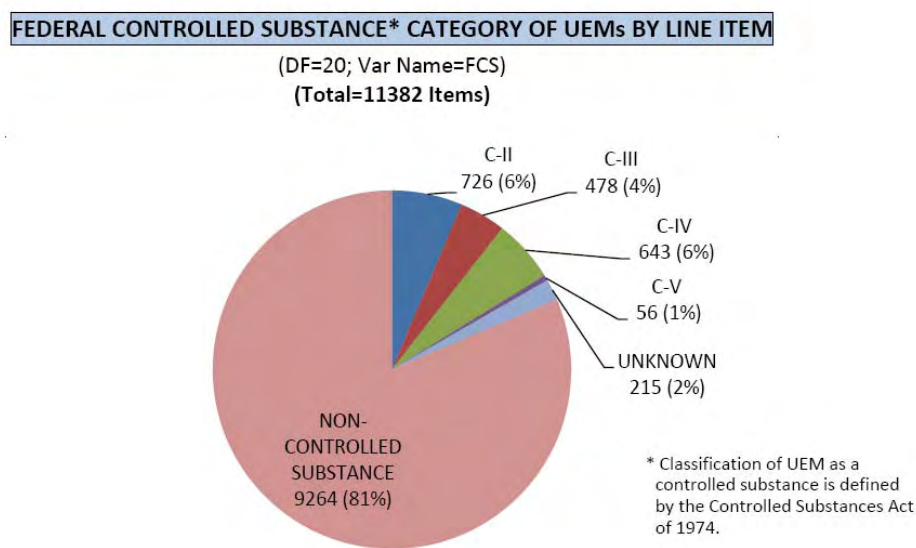
Most participants (77%) indicated that concern for the environment was a significant factor in their decision to use the mailback program and 16% cited safety for themselves and their families.

Figure 19. Disposal Methods Used Prior to Mailback Program



A very important source of data about our program came from the cataloguing of the drugs themselves. We received mostly pills, but also gels, creams, inhalers, and other items. Nearly all (86%) of the returns were prescription drugs, and 12% over-the-counter. The vast majority of returns represented prescription drugs consumed by humans as compared to the negligible amount of veterinarian medicines returned using the program.

Figure 20. Controlled Drug Status of Returned Medicine



About 17% of the drugs were schedules II, III, and IV –“controlled drugs.” These include narcotic pain relievers, tranquilizers and sedatives, as well as stimulants. These are the drugs that are sometimes diverted for “street” use or sale. Controlled substances were equally likely to be returned by males (14%) and females (15%) (no statistically significant difference). The rate of controlled substances returned increased slightly with age, but the differences were not significant.

Figure 21. Over-the-County Returns vs. Prescription Medicines

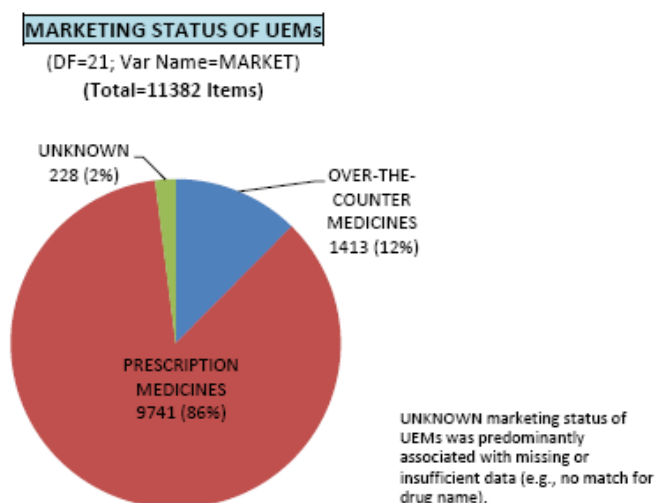
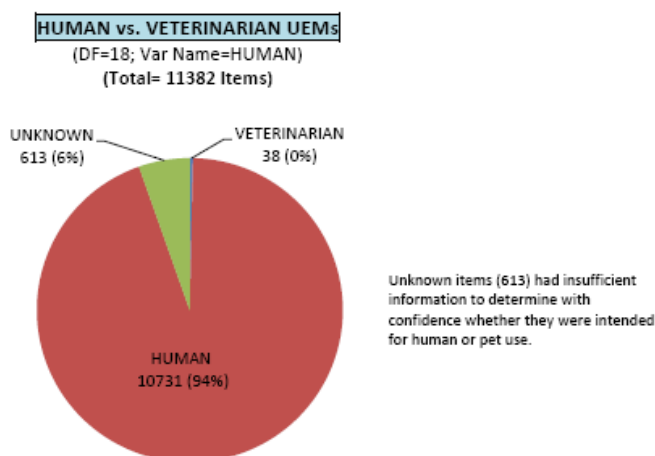
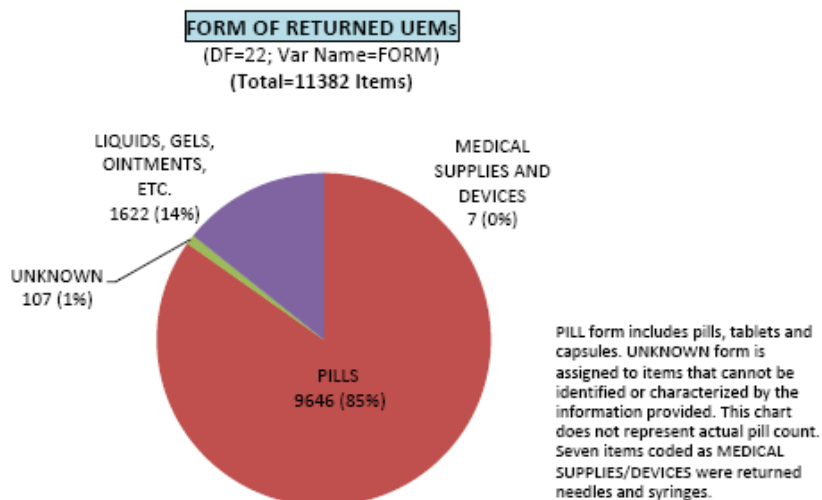


Figure 22. Human vs. Veterinarian Medicines Returned



Most returns were in pill form. Fourteen percent of returns represented liquids, gels, ointments and patches. A negligible amount of medical supplies and devices were returned including unused morphine pumps.

Figure 23. Form of Returned Medicines



Full, unused bottles were sometimes returned, including prescriptions from mail-order pharmacies or VA pharmacy services, as well as anti-retroviral drugs for HIV/AIDS treatment. It was not uncommon to find a mix of local and mail order pharmacies represented sometimes where a patient was receiving the same drug from both sources.

Drug data were classified into therapeutic categories by the Community Medical Foundation for Patient Safety using the Drug Abuse Warning Network system (DAWN). The following chart produced by the Community Medical Foundation for Patient Safety demonstrates that the CNS agents, cardiovascular agents, and psychotherapeutic agents were the top three categories of drugs returned through the program.

Figure 24. Therapeutic Category Breakouts of Returned Drugs by Number of Prescriptions/Medications Collected

THERAPEUTIC CATEGORY OF UEMs BY LINE ITEM

(DF=15; Var Name=THERCAT)

| THERAPEUTIC CATEGORY | COUNT | % |
|-------------------------------|--------------|------------|
| CNS AGENTS | 2613 | 22.96 |
| CARDIOVASCULAR AGENTS | 1687 | 14.82 |
| PSYCHOTHERAPEUTIC AGENTS | 1672 | 14.69 |
| RESPIRATORY AGENTS | 789 | 6.93 |
| ANTI-INFECTIVES | 776 | 6.82 |
| METABOLIC AGENTS | 765 | 6.72 |
| GASTROINTESTINAL AGENTS | 733 | 6.44 |
| TOPICAL AGENTS | 561 | 4.93 |
| HORMONES | 441 | 3.87 |
| NUTRITIONAL PRODUCTS | 377 | 3.31 |
| DATA MISSION/CATEGORY UNKNOWN | 328 | 2.88 |
| DRUG UNKNOWN | 172 | 1.51 |
| MISCELLANEOUS AGENTS | 169 | 1.48 |
| COAGULATION MODIFIERS | 168 | 1.48 |
| ALTERNATIVE MEDICINES | 59 | 0.52 |
| ANTINEOPLASTICS | 42 | 0.37 |
| IMMUNOLOGIC AGENTS | 12 | 0.11 |
| OTHER | 12 | 0.11 |
| NON-ALCOHOL ILLICITS | 5 | 0.04 |
| BIOLOGICALS | 1 | 0.01 |
| (blank) | | |
| Grand Total | 11382 | 100 |

Difference Noted on Therapeutic Classes of Drugs Returned

A subset of data was examined to determine gender and age-related differences among users and the drugs they returned:

- Males returned more anti-infectives, cardiovascular agents and metabolic agents.
- Females returned more gastrointestinal agents, hormones, psychotherapeutic agents and respiratory agents [Chi sq. = 39.52, df = 14, p < .000].
- Participants 50 years of age and younger were less likely than their older counterparts to return most classes of drugs, with the exception of psychotherapeutic agents.
- Top drug classes by age are as follows: Participants 75 or older: cardiovascular agents (19%); 65 to 74: hormones (7%); 50-64: metabolic agents (17%).

Figure 25. Therapeutic Subclass Breakouts of Returned Drugs by Number of Prescriptions/Medications Collected

FREQUENCY COUNT BY THERAPEUTIC CATEGORY, THERAPEUTIC SUBCLASS 1,

THERAPEUTIC SUBCLASS 2

(Total=11382 Items)

| THERAPEUTIC CATEGORY-- Therapeutic Subclass 1 | Count of Therapeutic Category | % |
|--|-------------------------------------|-------------|
| No therapeutic category available | 328 | 2.88 |
| ALTERNATIVE MEDICINES | 59 | 0.52 |
| Drug names not available | 6 | |
| Herbal products | 26 | |
| Nutraceutical products | 19 | |
| Probiotics | 8 | |
| ANTI-INFECTIVES | 776 | 6.82 |
| Drug names not available | 4 | |
| Amebicides | 42 | |
| Aminoglycosides | 10 | |
| Anthelmintics | 1 | |
| Antifungals | 62 | |

| | | |
|---|-------------|--------------|
| Antifungals, Azole antifungals | 12 | |
| Antimalarial agents | 8 | |
| Antituberculosis agents | 1 | |
| Antiviral agents | 33 | |
| Cephalosporins | 97 | |
| Cephalosporins, First generation | | |
| cephalosporins | 16 | |
| Dermatological agents | 1 | |
| Leprostatics | 1 | |
| Lincomycin derivatives | 27 | |
| Macrolide derivatives | 72 | |
| Miscellaneous antibiotics | 5 | |
| Penicillins | 151 | |
| Quinolones | 97 | |
| Sulfonamides | 57 | |
| Tetracyclines | 54 | |
| Urinary anti-infectives | 25 | |
| ANTINEOPLASTICS | 42 | 0.37 |
| Antimetabolites | 3 | |
| Hormones/antineoplastics | 37 | |
| Tyrosine kinase inhibitors | 2 | |
| BIOLOGICALS | 1 | 0.01 |
| In vivo diagnostic biologicals | 1 | |
| CARDIOVASCULAR AGENTS | 1687 | 14.82 |
| Drug names not available | 1 | |
| Antiadrenergic agents, centrally acting | 32 | |
| Beta-adrenergic blocking agents | 287 | |
| Calcium channel blocking agents | 194 | |
| Calcium channel blocking agents, | 21 | |
| Cardiovascular agents NTA | 671 | |
| Cardiovascular agents NTA, | | |
| Angiotensin converting enzyme inhibitors | 121 | |
| Cardiovascular agents NTA, | | |
| Angiotensin II inhibitors | 8 | |
| Cardiovascular agents NTA, Inotropic agents | 2 | |
| Diuretics | 350 | |
| CNS AGENTS | 2613 | 22.96 |
| Drug names not available | | |
| Analgesics | 1991 | |
| Analgesics, Miscellaneous | 4 | |

| | | |
|--|------------|-------------|
| analgesics/combinations | | |
| Analgesics, Nonsteroidal anti-inflammatory agents | 1 | |
| Anorexiant | 2 | |
| Anticonvulsants | 231 | |
| Anticonvulsants, Fatty acid derivative anticonvulsants | 26 | |
| Antiemetic/antivertigo agents | 123 | |
| Antiparkinson agents | 50 | |
| Miscellaneous CNS agents | 76 | |
| Muscle relaxants | 101 | |
| Muscle relaxants, Skeletal muscle relaxants | 6 | |
| COAGULATION MODIFIERS | 168 | 1.48 |
| Anticoagulants | 122 | |
| Antiplatelet agents | 39 | |
| Miscellaneous coagulation modifiers | 7 | |
| DRUG UNKNOWN | 172 | 1.51 |
| GASTROINTESTINAL AGENTS | 733 | 6.44 |
| Drug names not available | 6 | |
| 5-aminosalicylates | 15 | |
| Antacids | 18 | |
| Antidiarrheals | 65 | |
| Digestive enzymes | 14 | |
| Functional bowel disorder agents | 50 | |
| Functional bowel disorder agents, Serotonergic neuroenteric modulators | 2 | |
| Gallstone solubilizing agents | 5 | |
| GI stimulants | 41 | |
| H2 antagonists | 78 | |
| Laxatives | 172 | |
| Laxatives | 4 | |
| Miscellaneous GI agents | 28 | |
| Proton pump inhibitors | 235 | |
| HORMONES | 441 | 3.87 |
| Drug names not available | 1 | |
| Adrenal cortical steroids | 170 | |
| Bisphosphonates | 29 | |
| Miscellaneous hormones | 22 | |
| Sex hormones | 110 | |
| Sex hormones, Contraceptives | 2 | |
| Thyroid drugs | 82 | |

| | | |
|---|-------------|--------------|
| Thyroid drugs | 25 | |
| IMMUNOLOGIC AGENTS | 12 | 0.11 |
| Bacterial vaccines | 1 | |
| Immunosuppressive agents | 9 | |
| Viral vaccines | 2 | |
| METABOLIC AGENTS | 765 | 6.72 |
| Drug names not available | 6 | |
| Antidiabetic agents | 284 | |
| Antigout agents | 63 | |
| Antihyperlipidemic agents | 382 | |
| Antihyperlipidemic agents, HMG-CoA reductase inhibitors | 21 | |
| Glucose elevating Agents | 9 | |
| MISCELLANEOUS AGENTS | 169 | 1.48 |
| Drug names not available | 13 | |
| Antidotes | 5 | |
| Antirheumatics | 3 | |
| Chelating agents | 3 | |
| Genitourinary tract agents | 100 | |
| Miscellaneous uncategorized agents | 29 | |
| Smoking cessation agents | 15 | |
| Viscosupplementation agents | 1 | |
| NON-ALCOHOL ILLICITS | 5 | 0.04 |
| Stimulants | 5 | |
| NUTRITIONAL PRODUCTS | 377 | 3.31 |
| Misc | 19 | |
| Iron products | 9 | |
| Minerals and electrolytes | 145 | |
| Oral nutritional supplements | 1 | |
| Vitamin and mineral combinations | 86 | |
| Vitamins | 117 | |
| OTHER | 12 | 0.11 |
| PSYCHOTHERAPEUTIC AGENTS | 1672 | 14.69 |
| Antidepressants | 610 | |
| Antipsychotics | 300 | |
| Antipsychotics, Miscellaneous antipsychotic agents | 27 | |
| Anxiolytics, sedatives, and hypnotics | 565 | |
| CNS stimulants | 170 | |
| RESPIRATORY AGENTS | 789 | 6.93 |
| Drug names not available | 1 | |
| Antihistamines | 180 | |

| | | |
|---|--------------|---------------|
| Bronchodilators | 275 | |
| Decongestants | 36 | |
| Expectorants | 13 | |
| Respiratory agents NTA | 123 | |
| Upper respiratory | 1 | |
| Upper respiratory combinations | 160 | |
| TOPICAL AGENTS | 561 | 4.93 |
| Drug names not available | 7 | |
| Anorectal preparations | 6 | |
| Antiseptic and germicides | 8 | |
| Dermatological agents | 209 | |
| Dermatological agents, Topical antibiotics | 3 | |
| Mouth and throat products | 10 | |
| Nasal preparations | 80 | |
| Ophthalmic preparations | 198 | |
| Ophthalmic preparations, Ophthalmic glaucoma agents | 12 | |
| Otic preparations | 11 | |
| Vaginal preparations | 17 | |
| Grand Total | 11382 | 100.00 |

Through research both the environmental risk and the environmental hazards of the drugs returned through the program were assessed. All items for which data were available were found to pose at least some environmental risk. Environmental risk refers to risk of acute toxicity to the aquatic environment. Environmental risk is based on the ratio of predicted environmental concentration of the substance (PEC) and the highest concentration of the substance that does not have a harmful effect in the environment (PNEC)²³. Environmental Risk is specified as follow:

| Risk | Condition | Value |
|---------------|-------------|-------|
| Insignificant | if PEC/PNEC | <0.1 |
| Low | if PEC/PNEC | 0.1–1 |
| Moderate | if PEC/PNEC | 1–10 |

²³ More detailed information is available at www.fass.se and www.janusinfo.org/imcms/servlet/GetDoc?meta_id=7236

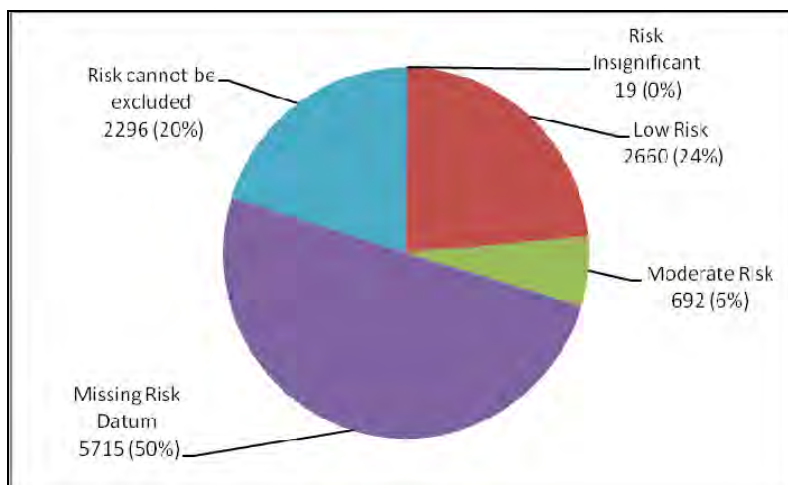
High if PEC/PNEC >10

Figure 26. Potential Environmental Risk of Returned Medicine

POTENTIAL ENVIRONMENTAL RISK

(DF=33, Var Name=RISK)

(Total=11382 Items)

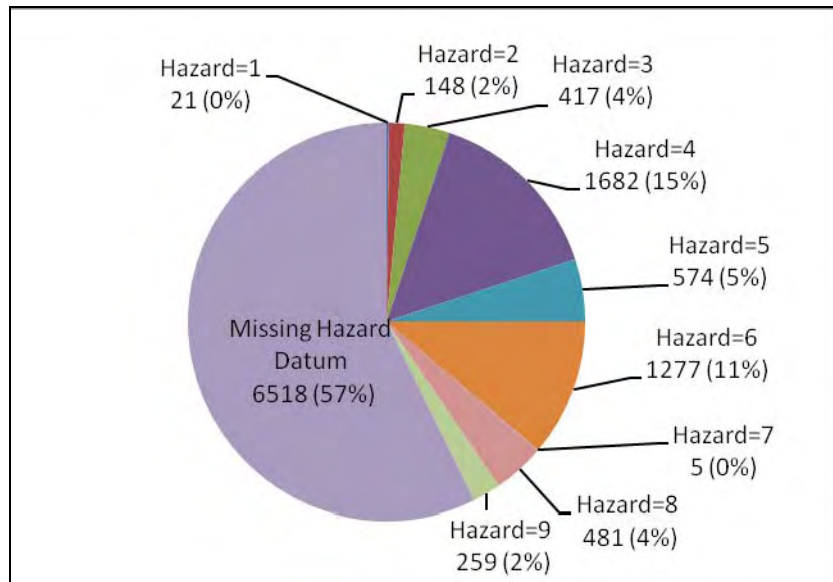


The potential environmental hazard assessment of the active pharmaceutical substance is based on the three characteristics of persistence (P), bioaccumulation (B), and toxicity (T). Each characteristic is assigned a numeric value (0–3). The total of the values comprises the PBT Index of the substance with 0 being the lowest PBT rating and 9 being the highest score representing the highest degree of environmental hazard. Environmental hazard assessment is based on the JANUS Classification System, accessed at http://www.janusinfo.se/imcms/servlet/GetDoc?meta_id=6913.

JANUS Classification System (Janusinfo) is a public-domain website that provides drug information to support healthcare professionals and environmental scientists to understand better the wide range of pharmaceutical products and their potential impact on the environment. The Drug Therapeutic Committees and the Department of Drug Management and Informatics in Stockholm County Council, Sweden maintain this website and periodically update the information.

Figure 27. Potential Environmental Hazard Posed by Returned Medicine

POTENTIAL ENVIRONMENTAL HAZARD
 (DF=34, Var Name=PBT; DF=35, P; DF=36,B; DF=37,T)
 (Total=11382 Items)



Classification is made of both the medicines' inherent ability to affect the environment (environmental hazard) and the environmental risk posed by the pharmaceutical substances when used to their current extent. The Environmental Department of Stockholm's County Council initiated the environmental hazard assessment based on data submitted by pharmaceutical manufacturers in 2003. The classification system includes environmental risk assessment, which was conducted by the Swedish Association of the Pharmaceutical Industry in 2005.

While the Swedish and European pharmaceutical market overlaps with that of the U.S., some medicines (generic categories) available in the U.S. may not be listed in the current JANUSINFO. Project Investigators along with the Community Medical Foundation for Patient Safety researched and evaluated many classification systems for the National Unused and Expired Medicines Registry and has determined that JANUSINFO is appropriate and efficient in characterizing the relative potential

environmental risk and hazard of UEMs. The scientific basis of JANUSINFO follows industry guidelines established by the U.S. Department of Health and Human Services, U.S. Food and Drug Administration, and the Organization for Economic and Co-operation for Development (OECD). OECD is a 30-country membership body established in 1961 to monitor, create standards, and present recommendations to help governments foster prosperity and fight poverty through economic growth and financial stability, as well as to ensure and address environmental implications of economic and social development.

In general, the standards and recommendations for environmental risk and hazard assessments are more stringent in Europe than those in the U.S. For more technical information and description of these standards, refer to the publication *Environmental Classification of Pharmaceuticals*.²⁴

Environmental risk and hazard data point to the need for disposal program options and communication campaigns that educate the public about the potential environmental impact of drugs that have been disposed of improperly. Findings from the mailback program indicate that, for drugs where environmental impact data were available, there was at least some risk or hazard present among the returns. Approximately 43% of the drugs collected were found to be a hazard to the environment and 50% of the returns presented environmental risk.

Conclusions

Maine's citizen mailback program has demonstrated that this approach is not only feasible, but effective. The program utilized a phased implementation, beginning by targeting elders and focusing on pharmacies as distribution sites for the mailback envelopes. We then phased in a broader target population, adults of all ages, as well as a broader range of distribution sites (other providers of health services).

²⁴ Contact the Community Medical Foundation for Patient Safety for more information: www.communityofcompetence.com

The mailback envelope take-back method returned a large quantity of drugs that would have otherwise been disposed of directly into the water system through flushing or into landfills through the trash. A short survey inserted in the envelope allowed us to track the reasons for participation, the sources of the drugs, and the demographic profile of the participants. This is information that is useful not only for project planning and education, but also policy development.

The mailback program provides a rich opportunity to educate a broad public citizenry about prescription drugs and the environment via community outreach and information distributed with the mailer. It involves citizens in an easy, “DIY” (do it yourself) problem-solving program that prevents environmental harm, prevents drug diversion, and prevents poisoning. Community education by older adults was found to be both effective and engaging while encouraging new users of the program to spread the word in their local communities. It is for this reason the consumer involvement should be a key component in any drug return program model.

The major challenge for this and other disposal programs continues to be funding to sustain such efforts. All disposal programming, whether mailback or event-based takeback programs, require a considerable amount of time and effort to plan, execute, and educate the public. Our first two phases have shown us that the interest and the community need exist and in fact, clearly outweigh the resources available to address the issue of drug disposal. However, it is imperative to continue as many programming and outreach efforts as possible to provide drug disposal options directly to the consumer at the same time that information is disseminated so as to avoid the confusion and misinformation the surrounds the issue of drug disposal.

APPENDICES

- APPENDIX 1: Contact Information
- APPENDIX 2: Project Collaboration/Partnerships and Leveraged Resources
- APPENDIX 3: Project Timeline
- APPENDIX GROUP 4: Contextual and Technical Documents
 - APPENDIX 4A: 2003 Drug Disposal Group meeting minutes-Legislation development for disposal program
 - APPENDIX 4B: Final report of the Maine Drug Return Implementation Group established through LD 1826
 - APPENDIX 4C: U.S. Drug Enforcement Administration Program Review Letter
 - APPENDIX 4D: U.S. Postal Service and Maine Drug Enforcement Agency Test Agreement document
 - APPENDIX 4E: Northern New England Poison Center Medication Disposal Summary
 - APPENDIX 4F: Maine Medicaid program: summary of 15-day prescription policy
 - APPENDIX 4G & 4H: 2007 and 2008 Proper Drug Disposal Day Proclamation issued by Maine Governor John Baldacci
 - APPENDIX 4I: Athens Declaration and Istanbul Statement
 - APPENDIX 4J: Ruhoy and Gressitt paper abstract on reasons for drug disposal
 - APPENDIX 4K: Postal Service press release on VA mailback program in Baltimore, Washington, DC, and West Virginia
- APPENDIX GROUP 5: Distribution Site Materials
 - APPENDIX 5A: Recruitment letter
 - APPENDIX 5B: Welcome letter
 - APPENDIX 5C: Memo of Understanding letter
 - APPENDIX 5D: Memo of Understanding
 - APPENDIX 5E: Informational poster
 - APPENDIX 5F: Program question and answer guide
 - APPENDIX 5G: Sample site newsletter
- APPENDIX 6: Helpline and Volunteer Information
- APPENDIX Group 7: Participant Mailback Envelope Materials
 - APPENDIX 7A: Instruction booklet for preparing and returning medicine
 - APPENDIX 7B: Informed consent for consumer survey
 - APPENDIX 7C: Consumer survey
- APPENDIX GROUP 8: Consumer and Community Education Items
 - APPENDIX 8A: Sign-in sheet
 - APPENDIX 8B: PowerPoint presentation
 - APPENDIX 8C: Program information handout
 - APPENDIX 8D: Community presentation evaluation form
 - APPENDIX 8E: Guidelines for community volunteers
 - APPENDIX 8F: Self-report timesheet for community volunteers
- APPENDIX GROUP 9: Marketing and Outreach Materials
 - APPENDIX 9A: Consumer fact sheet
 - APPENDIX 9B: Detailed fact sheet
 - APPENDIX 9C: Program brochure
 - APPENDIX 9D: Program summary sheet
 - APPENDIX 9E: Program business cards
 - APPENDIX 9F: April 2007 program press release
 - APPENDIX 9G: July 2009 program press release
 - APPENDIX 9H: Sample press release for local communities

- APPENDIX 9I: Save the date announcement for the 2008 International Symposium on Pharmaceuticals in the Home and Environment
- APPENDIX 9J: Save the date announcement for the 2009 International Conference on Safe Medicine
- APPENDIX 9K: List of program-related publications and presentations

APPENDIX 1

Safe Medicine Disposal for ME

Contact Information

Daily operations:

Jennifer Crittenden, M.S.W.
Project Director

Research Associate
UMaine Center on Aging
jennifer.crittenden@umit.maine.edu
207-262-7923

Project administration:

Lenard Kaye, D.S.W./Ph.D.
Principal Investigator

Director and Professor
UMaine Center on Aging
len.kaye@umit.maine.edu
207-262-7922

Technical/Scientific issues:

Stevan Gressitt, M.D.
Co-Principal Investigator
Medical Director, Adult Mental Health Services
Maine Department of Health and Human Services
stevan.gressitt@maine.gov
207-287-4273

General Project Information:

Phone: 1-866-ME-RX-RID (1-866-637-9743)
Email: info@safemeddisposal.com
Website: www.safemeddisposal.com

APPENDIX 2

Project Collaborations/Partnerships and Leveraged Resources

Maine-Based Organizations

- Center on Aging, University of Maine
- Maine Association of Psychiatric Physicians
- Maine Benzodiazepine Study Group (MBSG) & Drug Disposal Group
- Maine Council for Child & Adolescent Psychiatry
- Maine Department of Health and Human Services
- Maine Department of Environmental Protection
- Maine Drug Enforcement Agency
- Maine Office of Adult Mental Health Services
- Maine Office of Substance Abuse
- Maine Center for Disease Control and Prevention
- Maine Office of the Attorney General
- Maine Office of Elder Services
- Maine Pharmacy Association
- Independent pharmacies throughout Maine
- Maine Retired Senior Volunteer (RSVP) Programs
- Margaret Chase Smith Center Policy Center, University of Maine
- Northern New England Poison Center
- Husson University School of Pharmacy
- University of New England
- Maine Medical Association
- Safe Medicine for Maine

Federal & National Organizations

- American Pharmacists Association
- Community Medical Foundation for Patient Safety
- National Council on Patient Information and Education
- Office of the U.S. Attorney General
- Rite Aid Corporation
- CVS Pharmacies
- U.S. Drug Enforcement Administration
- U.S. Environmental Protection Agency Aging Initiative
- U.S. Postal Service
- Villanova University Center for the Environment

APPENDIX 3

Project Timeline: Phases I & II of Pilot

- Create consolidation, transportation, and incineration protocols
- Commence meetings of technical advisory task force
- Secure network of 75 distribution points (pharmacies) to which mailers are distributed in both phases
- Engage community advisory board members
- Commence meetings of community advisory board
- Design and create mailers and accompanying survey, training materials for Distribution Site Educators and instructions for pharmacies and public
- Create web site, establish 800 number call center and create related training materials and protocols
- Engage and train Distribution Site Educators
- Develop education campaign content and communication dissemination plan
- Launch Phase I education campaign
- Distribute informational materials for pharmacists, staff, and individuals acquiring mailers for Phase I; provide training
- Collect, inventory and destroy returned products in compliance with applicable state and federal laws and sound environmental practices in four-county region for Phase I
- Contract with incineration facilities and transportation contractors
- Evaluate Phase I and refine for Phase II
- Launch Phase II education campaign
- Distribute informational materials for pharmacists, staff, and individuals acquiring mailers for Phase II; provide training
- Collect, inventory and destroy returned products in compliance with applicable state and federal laws and sound environmental practices statewide for Phase II
- Generate, analyze and report on survey and inventory data in a manner that allows physicians, pharmacists, insurance companies, patients and others to modify behaviors to minimize unused medications
- Conduct final evaluation of project
- Publish best practices guidebook

APPENDIX GROUP 4

Contextual and Technical Documents

- APPENDIX GROUP 4: Contextual, legal and technical documents and agreements that link the project with the following:
 - APPENDIX 4A: 2003 Drug Disposal Group meeting minutes-Legislation development for disposal program
 - APPENDIX 4B: Final report of the Maine Drug Return Implementation Group established through LD 1826
 - APPENDIX 4C: U.S. Drug Enforcement Administration Program Review Letter
 - APPENDIX 4D: U.S. Postal Service and Maine Drug Enforcement Agency Test Agreement document
 - APPENDIX 4E: Northern New England Poison Center Medication Disposal Summary
 - APPENDIX 4F: Maine Medicaid program: summary of 15-day prescription policy
 - APPENDIX 4G & 4H: 2007 and 2008 Proper Drug Disposal Day Proclamation issued by Maine Governor John Baldacci
 - APPENDIX 4I: Athens Declaration and Istanbul Statement
 - APPENDIX 4J: Ruhoy and Gressitt paper abstract on reasons for drug disposal
 - APPENDIX 4K: Postal Service press release on VA mailback program in Baltimore, Washington, DC, and West Virginia

Drug Disposal Group
Interested Parties Meeting

December 16, 2003

Attached is the attendance list.

Introductory Remarks

Senator Lynn Bromley opened the meeting at 10am. She noted that her goal was to pass a bill on this issue, hoping to come out of today's meeting with an outline. Her deadline for drafting legislation is January 6 at the Revisor's Office. Let's not make perfect the enemy of the good, she suggested.

The group represented a wide variety of constituencies and viewpoints. As individuals introduced themselves and stated their reasons for attending the meeting, Senator Bromley noted the priority categories into which they fell. Seven said they were here for diversion issues, nine regarding waste issues, five for education, three for mistaken prescriptions, and two for security issues.

Karen Simone from the Poison Center noted that the center would support anything environmentally sound, as they used to recommend flushing because of the speed with which you could get rid of it. She noted that garbage cans are not safe for kids and are often raided by drug abusers. We need to make sure we're not making these drugs more accessible.

Many members of the state's environmental community, including the state's fish pathologist, biologist, as well as the state geologist, attended and raised concerns regarding the impact of drug disposal on groundwater. They noted that a lot of work is being done on the downstream effects of flushing prescription drugs. Ann Pistell of the DEP said that they deal a lot with product stewardship issues, which has a role in this discussion. Scott Austin of the DEP noted that he deals with hospitals on this issue and that there are no hospital incinerators left in Maine.

We were joined by Laurie Tenace of Florida who is working on this issue regarding pharmaceuticals and personal care products. She is scheduling a teleconference on this issue in January.

The Rite-Aid representative noted that we need to find out what the Federal regs were for scheduled drugs and that an appropriate method for paying for this needed to be found.

Marci Sorg, from the Margaret Chase Smith Center, was involved in the drug mortality/morbidity studies recently and works with the state medical examiner. She has seen the results of a lot of mistakes, especially in the elderly.

Ann Robinson, representing Pharma, noted that diversion is an issue with today's children, stressing that drugs ought to be taken by those to whom they were prescribed. The science issues are complex and emerging with lots to be learned. She advised the group to proceed with caution.

Jim Cameron from the Maine Attorney General's Office is concerned about diversion, noting that Schedule II drugs have a huge street value. A collection mechanism must keep this in mind. Security must be built in.

Pharmacies, represented by both Jim MacGregor of the Maine Merchants Association, and Bob Morissette, noted that reverse distribution is a common practice.

Current Practices

Scott Austin noted that there are some current requirements, including RCRA, which controls toxic drugs (chemotherapy, etc) and the DEA, which dictates controlled drug disposal. He noted the need to involve the State Board of Pharmacy. The Maine Hospital Association has identified alternatives to incineration. Scott noted that there would be some pollution concerns. Steam sterilization is a cleaner non-incineration option for waste but not for drugs.

It was noted that law enforcement incinerates at 1800 degrees. They incinerate evidence, both pills and marijuana, totaling 9.1 tons per year. This is mostly marijuana. It was also noted that chemo drugs cannot be incinerated.

Ann Pistell noted that the USGS has identified pharmaceuticals in the water. The EPA is doing a sampling and we should have results by the end of the month.

Suggestions for Legislation

Dr. Gressit told the group that the DEA has said that controlled drugs cannot be returned to pharmacies and other providers. Apparently specific licensed individuals cannot handle these as returns. He suggested a mail-back program where a packet would go to the post office and the DEA could empty the box and dispose of the contents appropriately.

Ann Pistell suggested considering product stewardship. The returns could go back to the pharmaceuticals, similar to the mercury switch law. She also suggested that perhaps they could be handled as hazardous waste and be collected as such. The group discussed this but concerns over the safety of handling the drugs were prevalent.

Marci Sorg cautioned the group to consider HIPPA issues.

Senator Bromley threw out the idea of doing a pilot program with one drug but the idea was dismissed. All prescription drugs would be preferable.

The group agreed that incineration would be worth pursuing. However, the “air people” at DEP need to be able to weigh in on this. Extra manpower and resources would be needed for this. Having the DEA incinerate would satisfy the licensing question.

The DEP suggested that Maine needs better waste control treatment plants, which should be the subject of a separate bill.

Roy McInney of the MDEA had a number of comments. 1) From a public safety standpoint, the MDEA would like to be of assistance, as long as it does not endanger its core mission, which is to reduce the drug supply through identification and prosecution of drug traffickers. 2) MDEA has a central evidence facility, which has 5000 individual exhibits collected each year. They dispose of these through incineration. Approx 9 tons were destroyed last year. 3) We must find funding for using MDEA’s infrastructure. It’s \$88/ton for destruction. And the cost of staff needs to be covered. They would need two people and a vehicle to do this. Roy was interested in finding out how much volume we’re expecting but this number was too hard to discern (somewhere between 5000 and 10000 pounds was suggested).

The public health nurse asked the group what they thought of including veterinarian medications. The group seemed interested and agreed to include them.

Focusing the Legislation

Senator Bromley suggested that the legislation be a pilot program. Marci Sorg was solicited to suggest particular counties where diversion was the worst and she recommended Cumberland and Washington. However, Anna Bragdon suggested that we ask for a statewide program and only reduce it to a pilot program if need be.

Dr. Gressit suggested using school districts to distribute information and mailers.

Marci Sorg suggested that there may be federal dollars and money from drug manufacturers. Jim Cameron noted that the manufacturers have foundations. We would need to determine how we would use the money before we asked. It’s important to have no strings attached. He suggested Purdue Pharma and Pfizer.

It was suggested that we poll the state for current disposal behaviors. There is a statewide survey already done which we could add a question to for a fee. It is sent to 4000 Maine residents.

The group discussed doing a random opening of 100 packages to learn from them. We could translate found pills into actual dollars. The Poison Center could do the research on the pills with some staff help. There may be privacy issues that need to be addressed.

Issues needing further attention

Postal inspectors

Liquids

Committee referral – HHS

Mobilization of support (including AARP)

Research aspect

Rules should be minor technical.

Conclusion

Senator Bromley wrapped up the meeting by reviewing the group's progress. A bill will be drafted which will call for mailers for returned prescriptions to be destroyed by the MDEA. It will include veterinary meds and the rules will not be major substantive.

**STATE OF MAINE
122nd LEGISLATURE
FIRST REGULAR SESSION**

**Final Report
of the
MAINE DRUG RETURN IMPLEMENTATION
GROUP**

March 8, 2005

Staff:

**Danielle Fox, Legislative Analyst
Jane Orbeton, Legislative Analyst
Office of Policy & Legal Analysis
Maine Legislature
(207) 287-1670**

Members:

**Sen. John L. Martin, Chair
Katherine Bilotas
James Cameron
Douglas S. Carr
William M. Earle
Stevan Gressitt
Susanne P. Ketterer
Roy McKinney
Sally-Lou Patterson
Ann Pistell
James Toman**

Table of Contents

| | Page |
|---|----------|
| Executive Summary | i |
| I. Introduction..... | 1 |
| II. Background information | 1 |
| A. Defining the problem | |
| B. Environmental issues | |
| C. Federal and state requirements | |
| Hazardous waste | |
| Disposal | |
| Postal requirements | |
| D. Current approaches | |
| III. Recommendations | 5 |
| A. Voluntary turn-in events | |
| B. Mail-in program | |
| C. Product stewardship | |
| D. General recommendations | |
| Appendices | |
| A. Authorizing Legislation, Public Law 2003, Chapter 679, An Act to Encourage the Proper Disposal of Unneeded Pharmaceuticals | |
| B. Membership list, Maine Drug Return Implementation Group | |
| C. Chart of options for drug return programs | |
| D. Origins and Fate of PPCPs in the Environment by Christian G. Daughton | |
| E. An Act Regarding the Disposal of Unused Pharmaceuticals | |
| F. An Act to Establish the Unused Prescription Drug Redistribution Program | |

Executive Summary

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. The public law is included in Appendix A.

History

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, representatives of Maine police chiefs, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. The membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, to receive briefings and to reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

Recommendations

- The implementation group recommends the encouragement of local turn-in events for people to drop off unneeded pharmaceuticals for disposal. These programs rely on the voluntary action of individuals, local municipalities, community service organizations and law enforcement agencies for success. The implementation group suggests that the Legislature consider product stewardship, in which the pharmaceutical manufacturers would fund or provide funding for all aspects of local turn-in events.
- The implementation group recommends amendments to the Maine Unused Pharmaceutical Disposal Program, Public Law 2003, Chapter 679, to allow public funding that is not from the General Fund and delay the start date to July 1, 2006. See draft legislation in Appendix E. Once again, product stewardship could be considered to provide funding for the mail-in program.
- The implementation group supports consideration of a drug redistribution program that would accept unneeded, unopened prescription drugs for redistribution to qualified persons who hold prescriptions for those drugs. See Appendix F.
- The implementation group recommends that the Maine Drug Enforcement Agency send a letter to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide a safe and effective method of disposal for controlled substances for individual citizens and law enforcement.

I. INTRODUCTION

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. A copy of Public Law 2003, Chapter 679, is attached as Appendix A.

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, and representatives of a local police department, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. In addition, the implementation group maintained contact with and invited the participation of representatives of the Office of the United States Attorney for Maine, the United States Drug Enforcement Administration in the United States Department of Justice and the United States Postal Service. A copy of the membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, receive briefings on state pharmaceutical programs and state and federal law and reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

II. BACKGROUND INFORMATION

A. Defining the problem

Unneeded prescription drugs can be a problem. Kept at home, they stack up in the medicine cabinet, age beyond their expiration dates and tempt unsafe use and intentional abuse. Newspaper accounts offer frightening accounts of home invasions with the intent of obtaining prescription narcotics such as OxyContin. Pharmacies are reluctant to take back unneeded drugs or are prohibited by law from doing so. Disposing of unneeded drugs by flushing them down the toilet or discarding them in the trashcan, so that they end up in a landfill, carries risks to the environment. What is a person to do?

B. Environmental issues

Evidence of pharmaceuticals and personal care products (PPCPs) is showing up in tests conducted on various bodies of water around the globe. Scientific testing points to the need for more research, increased public awareness and better stewardship of the world's surface and groundwaters. A leading researcher on PPCPs, Christian Daughton, of the US Environmental Agency, National Exposure Research Laboratory, has called for increased collaboration between

the environmental and medical fields to determine the causes, extent, risks and solutions to the issue of drugs as pollutants. (*Environmental Stewardship and Drugs as Pollutants*, The Lancet, October 5, 2002, by Christian G. Daughton)

Following are some examples of studies on pharmaceuticals and personal care products and their findings:

- Traces of pharmaceuticals and personal care products have been found by the US Geological Survey downstream of wastewater treatment plants and livestock farms in 139 rivers in 30 states. (*Algae Laid Low by Soap and Toothpaste*, Science Update, November 14, 2004 by Hannah Hoag, citing research by Dana Kolpin in 1999 and 2000) Researchers tested for 95 different organic compounds found in pharmaceuticals and household chemicals. At least one of the target organic compounds showed up in 80% of the waterways, with an average of 7 organic compounds per stream and a maximum of 38 organic compounds in one stream.
- Chemicals that find their ways into streams, by way of sewage, and that are not effectively destroyed by sewage treatment plants include antibiotics, antidepressants, anti-cancer drugs, tranquilizers, blood lipid regulators and other well-known drugs such as Viagra. (*Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* Environmental Health Perspectives, December 1999 by Christian Daughton and Thomas Ternes)
- One NuvaRing women's controlled release estrogen dispenser contains after use 2.4 milligrams of estrogen, enough to interfere with the reproduction systems of fish. (*Contraceptive Ring Could Pose Risks After Its Disposal*, Science News, January 25, 2004, by Janet Raloff)

The scientific community recognizes that further research is warranted on the environmental impact of pharmaceuticals and personal care products that reach the environment through excretion from the body, washing dermally applied medications or disposal through flushing or landfilling. Some deposition is inevitable as wastewater cannot treat for most pharmaceuticals and personal care products, but improper flushing is avoidable with consumer education and the development of sound disposal options.

C. Federal and state requirements

Hazardous waste

The Federal Resource Conservation and Recovery Act (RCRA) classifies household pharmaceuticals as household hazardous waste and exempts them from federal regulations governing the disposal of hazardous waste. Having adopted the provisions of RCRA, Maine has chosen to regulate household pharmaceuticals as solid waste, making disposal of unneeded drugs by a household member in a landfill or sewer system legal. When prescription drugs are separated from household waste and accumulated from more than one individual, those accumulated drugs are considered hazardous waste under state and federal laws and must be disposed of in compliance with those requirements.

A drug that is a controlled substance, categorized on a federal list as Schedule II through V, is viewed differently from pharmaceuticals that are not controlled substances. Once a controlled substance is in the hands of the prescription holder, a law enforcement agent in the course of conduct of official duties is authorized to accept that drug. The officer must dispose of accumulated controlled substances as hazardous waste through a witnessed burn at a licensed waste incinerator. Federal law prohibits all others, including reverse distributors, from accepting controlled substances from individuals and law enforcement officers, thus increasing the difficulty and cost of law enforcement in effecting disposal.

Some prescription and nonprescription drugs are considered hazardous waste because of their chemical make-up or characteristics. These drugs also must be disposed of as hazardous waste, at a licensed hazardous waste incinerator facility. If they are not controlled substances disposal does not have to be by a witnessed burn.

Mailing and shipping requirements

A program for mailing in unneeded prescription drugs must comply with federal requirements for mailing, following the US Postal Service Domestic Mail Manual and the rules adopted under that manual,. The program must also comply with any requirements from the Controlled Substances Act, the U.S. Environmental Protection Agency and the U.S. Drug Enforcement Administration. As prescription drugs already regularly travel via the mail in this country to consumers, the technology of appropriate packaging exists and is reasonably priced.

Sending accumulated unneeded prescription drugs out of state for disposal as hazardous waste requires the services of a licensed transporter of hazardous waste. The implementation group noted that hiring personnel to identify and separate controlled substances from other drugs could be very expensive but would lower disposal costs for the drugs that are not controlled substances. Not separating the drugs would save on substantial personnel costs and increase disposal costs as all of the drugs would have to be disposed of as if they were controlled substances.

D. Current approaches

Lacking clear direction on methods for disposing of unneeded prescription drugs, Maine residents choose a variety of approaches. They store them up at home, seek the cooperation of their dispensing pharmacy to take them back and dispose of them, flush them into the sewer and send them to the landfill or incinerator plant. The Penobscot County AARP Triad has just begun small scale turn-in events and a larger 1-day event held in South Portland at a pharmacy resulted in the collection of 55,000 pills, enough to fill a 55 gallon container. Public Law 2003, Chapter 679 establishes a mail-in program contingent on acquiring outside funding which is scheduled to begin July 1, 2005 if funding is available.

The implementation group reviewed the volume of drugs being prescribed, the practices of Maine's nursing facilities and hospitals and the requirements of the MaineCare program. Data presented to the group provided a snapshot of the type and amount of drugs being prescribed in the state. The implementation group appreciates the cooperation of the Maine Health Care

Association, the Maine Hospital Association, the MaineCare program within the Department of Health and Human Services, Anthem Blue Cross Blue Shield, the Maine State Employees Health Insurance Program, the University of Maine Systems health plan and the Maine Education Association Benefits Trust.

From the information provided, the implementation group considered the following items to be particularly useful when looking at the big picture of prescription drugs and their disposal:

- Maine's nursing facilities are aware of the problem of unneeded prescription drugs, of the need for safe disposal and the potential benefits of returning unneeded drugs. Controlled substances and medicines that come in bulk and formulations such as ointments and cortisone must be regularly and methodically destroyed. Unit doses that are unopened are returned to the pharmacy for credit and repackaging whenever possible. Handling of medications is done only by trained staff, with paperwork requirements and storage and dispensing procedures that would not be practical in a household setting.
- Maine's hospital pharmacies handle a broad array of prescription drugs. They utilize reverse distributors, which are companies that accept unused drugs, return whatever is possible to the manufacturers and dispose of expired and out of date drugs, drugs the manufacturers would not accept back and drugs on the federal RCRA list. Drugs that are not hazardous waste under Maine DEP rule may be managed as medical waste and incinerated. RCRA hazardous waste drugs are disposed of as hazardous waste and are shipped to disposal sites out of state. Unmedicated intravenous fluids and controlled substances are disposed of into the sewer system.
- The MaineCare program reimburses pharmacies and hospitals for prescription drugs for members enrolled in the MaineCare program. In order to avoid excess dispensing, MaineCare controls the length of time for which drugs may be dispensed, according to the nature of the drug. The program requires nursing and other health care facilities to identify unneeded drugs on a monthly basis, requires that drugs in unit dose packages be returned for credit and requires the destruction of unneeded medications not returned for credit.
- In order to learn the extent of prescription drug use in Maine, the implementation group reviewed the quantities of prescription drugs reimbursed each month by 3 large health coverage programs. The Maine State Employees Health Insurance Program reimburses pharmacies for an average of 136,427 prescriptions each month, of which 2193 are for narcotics. The Maine Education Association Benefits Trust reimburses pharmacies for an average of 205,474 prescriptions per month, of which 2629 are for narcotics. The University of Maine Systems health plan reimburses pharmacies for an average of 40,500 prescriptions per month, of which 533 are for narcotics.

III. RECOMMENDATIONS

A. Voluntary turn-in events

The implementation group reviewed voluntary turn-in events for unneeded prescription drugs and recommends encouraging turn-in events on the local level. The implementation group anticipates an increasing number of these events and greater amounts of collected unneeded drugs. The implementation group recommends that the Legislature consider product stewardship for voluntary turn-in events in order to provide continuing responsibility from pharmaceutical manufacturers for their products, including funding for education, outreach, collection, disposal and reporting.

Coordination

The implementation group recommends that the Maine Department of Environmental Protection, the Maine Drug Enforcement Agency, the Department of Health and Human Services and the Department of the Attorney General work together with manufacturers to enable more turn-in events to be held successfully. Coordination is needed to ensure that turn-in events are safe and convenient for individual citizens who participate, provide safeguards for the collection and identification of turned-in drugs and comply with state and federal law and rule regarding the handling of controlled substances and hazardous waste. The implementation group suggests that a statistically valid sampling of collected unneeded drugs be done and recorded to provide information about drug prescribing and waste.

Educational materials and outreach

The implementation group suggests that the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association and the Maine Hospital Association work together to prepare informational materials for interested parties, participating municipalities, law enforcement, medical personnel and community service organizations. Good information on how to successfully hold a voluntary turn-in event will increase the number of events, public participation and success.

Funding

Funding for collection, transportation, storage and disposal would enable a greater number of turn-in events to be held successfully. Funds may be needed for law enforcement, statistical sampling, reporting and disposal. The implementation group suggests that individuals and entities interested in voluntary turn-in events pursue funding for their local events and that the Legislature consider product stewardship to provide funding.

Starting date

A starting date for voluntary turn-in events is not required because of their voluntary nature. If product stewardship were applied to voluntary turn-in events, a start date would be needed for manufacturer responsibility to begin.

B. Mail-in program

Public Law 2003, Chapter 679, which created the Unused Pharmaceutical Disposal Program, recognized that the enabling legislation was incomplete and established the implementation group to provide guidance to the Legislature. Specifically the legislation mentions the need for recommendations regarding postal regulations, methods and requirements for mailing packaging, minimizing drug diversion and theft and public education. The implementation group reached consensus on recommendations to move the disposal program forward. The implementation group recommends that the Legislature consider adding a product stewardship model to the mail-in program.

Packaging for mailing

The implementation group suggests that pharmaceutical manufacturers or the State or both provide the mailing packaging for the mail-in program that meets the requirements of the United States Postal Service and the Maine Drug Enforcement Agency. The implementation group recommends that the mailing packaging be made available at pharmacies, hospitals, physicians' offices and health clinics.

Mail receipt, storage and disposal

The implementation group recommends that the Maine Drug Enforcement Agency determine whether drugs would be mailed directly to MDEA or to a consolidator under contract with MDEA. MDEA rulemaking is necessary to establish the protocols for mailers and mailing, statistical sampling and reporting and disposal of drugs. Transportation to a disposal site, which is required to be done by a licensed handler of hazardous waste, would be accomplished by the consolidator. Hazardous waste disposal sites would accept the shipments of unneeded drugs shipped from Maine and would dispose of them by incineration.

Educational materials and outreach

The implementation group suggests that educational materials for pharmaceutical manufacturers, pharmacies, hospitals, physicians' offices, health clinics, law enforcement and individual citizens be provided by the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association, the Maine Hospital Association and the drug manufacturers, all within the limits of their existing resources.

Funding

Public Law 2003, Chapter 679 requires non-public funding in order to begin the mail-in program. Funding will be required for the prepaid mailers, distribution, postage, storage and disposal and public education materials. The implementation group recommends that Public Law 2003, Chapter 679 be amended in 22 MRSA section 2700, subsection 5, to allow receipt of non-General Fund public funding, including federal funds. Suggested legislation is included as Appendix E.

Starting date

The implementation group recommends that the starting date for the Unused Pharmaceutical Disposal Program be changed to allow for additional preparation time for the adoption of rules and the acquisition of funding. The implementation group recommends that Public Law 2003, Chapter 679, section 4 should be amended to provide for an effective date of July 1, 2006. Suggested legislation is included as Appendix E.

C. Product stewardship

Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner. The implementation group recommends that the Legislature consider a product stewardship model for voluntary turn-in programs and the mail-in program for prescription drugs, recognizing the cooperative efforts of individual citizens, prescription drug manufacturers and State government to provide safe collection and disposal for those drugs. If product stewardship were to be adopted by the Legislature, the implementation group recommends a starting date of July 1, 2007.

D. General recommendations

- The implementation group recommends that the Maine Legislature consider legislation to establish a redistribution program for unneeded pharmaceuticals. Under this program Maine residents of low and medium income who hold a valid prescription would be eligible to obtain for a very low fee prescription drugs that had been donated to the program from health facilities, drug manufacturers, drug wholesale and terminal distributors and hospitals. The drugs would all be unopened and packaged in tamper-evident unit dose packages or they would be unopened injectable, aerosol or topical medications. The program would not distribute controlled substances, drugs that had been tampered with or drugs within 6 months of their expiration date. See Appendix F for suggested legislation.
- The implementation group recommends that a letter be sent by the Maine Drug Enforcement Agency to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide individual citizens and law enforcement safe and effective methods of disposal for controlled substances.

APPENDIX A

Public Law 2003, Chapter 679

An Act to Encourage the Proper Disposal of Unneeded Pharmaceuticals

APPROVED

CHAPTER

MAY 05 '04

679

BY GOVERNOR

PUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND AND FOUR

S.P. 671 - L.D. 1826

An Act To Encourage the Proper Disposal of Unused
Pharmaceuticals

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 604 is enacted to read:

CHAPTER 604

DISPOSAL OF UNUSED PHARMACEUTICALS

§2700. Unused Pharmaceutical Disposal Program

1. Establishment; purpose. There is established the Unused Pharmaceutical Disposal Program, referred to in this chapter as "the program." The purpose of the program is to ensure the safe, effective and proper disposal of unused pharmaceuticals. For purposes of compliance with federal law and regulation, the return of pharmaceuticals under this section is deemed to be for law enforcement purposes.

2. Administration. The program is administered by the Maine Drug Enforcement Agency, referred to in this chapter as "the agency," established in Title 25, section 2955.

3. Return of pharmaceuticals. The agency shall create a system for the return of unused pharmaceuticals. The system must use prepaid mailing envelopes into which the unused

pharmaceuticals are placed and returned to a single collection location. The prepaid mailing envelopes must be made available to the public at various locations, including, but not limited to, pharmacies, physicians' offices and post offices. The agency may randomly assess the toxicity of materials received under the program as long as the assessment results do not identify the patient, person who mailed the material, prescriber or pharmacy.

4. Disposal of pharmaceuticals. The agency shall ensure that only agency officers handle the unused pharmaceuticals received pursuant to subsection 3. The unused pharmaceuticals must be disposed of by the agency in a manner that is designed to be effective, secure and in compliance with local, state and federal environmental requirements, including the federal Resource Conservation and Recovery Act of 1976, as amended.

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund, nonpublic fund source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter.

6. Rulemaking. The agency shall adopt rules to carry out the purposes of this chapter. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Maine Drug Return Implementation Group. The Maine Drug Return Implementation Group, referred to in this section as "the implementation group," is established to work on implementation issues for the Unused Pharmaceutical Disposal Program, established in the Maine Revised Statutes, Title 22, chapter 604, referred to in this section as "the program."

1. Issues. The implementation group shall study the following issues and make recommendations for implementation of the program in a manner that addresses the issues, safeguards the public health and environment and meets the requirements of local, state and federal law, rule and regulation:

A. Postal regulations;

- B. The methods and requirements for packaging, including prepaid mailing envelopes;
- C. Minimizing drug diversion and theft;
- D. Public education regarding program requirements and operation; and
- E. Encouraging the development of drug drop-off programs at the local level.

2. Membership. The implementation group consists of 11 members.

A. The President of the Senate shall appoint one Senator, one representative of local municipal enforcement agencies and one representative of pharmacies. The appointed Senator serves as chair of the implementation group.

B. The Speaker of the House shall appoint 2 representatives, one person representing pharmaceutical manufacturers and one representative of a statewide association of medical professionals.

C. The implementation group must also include the Attorney General or the Attorney General's designee, the Commissioner of Human Services or the commissioner's designee, the Commissioner of Environmental Protection or the commissioner's designee and the Director of the Maine Drug Enforcement Agency or the director's designee.

The implementation group shall invite the participation of the federal Drug Enforcement Agency, the Office of the United States Attorney for the District of Maine, the United States Postal Service and interested parties and persons with expertise and interest in issues related to the disposal of unused pharmaceuticals.

All appointments must be made by September 1, 2004. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When appointment of all members of the implementation group is completed, the chair shall call and convene the first meeting no later than September 30, 2004.

3. Staffing. Staffing must be provided by a statewide association of medical professionals and, upon approval of the Legislative Council, the Office of Policy and Legal Analysis.

4. Compensation. Legislative members of the implementation group are entitled to the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2, and reimbursement for travel and other necessary expenses related to their attendance at authorized meetings of the group. Public members not otherwise compensated by their employers or other entities that they represent are entitled to receive reimbursement of necessary expenses and, upon a demonstration of financial hardship, a per diem equal to the legislative per diem for their attendance at authorized meetings of the implementation group.

5. Report. The implementation group shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters by January 31, 2005. The report must include information and recommendations on implementing the program. The joint standing committee of the Legislature having jurisdiction over health and human services matters shall review the report and may report out legislation to the First Regular Session of the 122nd Legislature.

6. Extension. If the implementation group requires a limited extension of time to conclude its study and make its report, it may apply to the Legislative Council, which may grant an extension.

7. Funding. The implementation group shall seek outside funds to fully fund all costs of the implementation group. If sufficient outside funding has not been received by September 15, 2004 to fully fund all costs of the implementation group, no meetings are authorized and no expenses of any kind may be incurred or reimbursed. Contributions to support the work of the implementation group may not be accepted from any party having a pecuniary or other vested interest in the outcome of the matters being studied. Any person, other than a state agency, desiring to make a financial or in-kind contribution must certify to the Legislative Council that it has no pecuniary or other vested interest in the outcome of the study. Such certification must be made in the manner prescribed by the Legislative Council. All contributions are subject to approval by the Legislative Council. All funds accepted must be forwarded to the Executive Director of the Legislative Council along with an accounting record that includes the amount of funds, the date the funds were received, from whom the funds were received and the purpose of and any limitation on the use of those funds. The Executive Director of the Legislative Council shall administer any funds received by the implementation group. The executive director shall notify the chair of the implementation group when sufficient funding has been received.

Sec. 3. Appropriations and allocations. The following appropriations and allocations are made.

LEGISLATURE

Miscellaneous Studies - Funding

Initiative: Allocates funds for the per diem and expenses of members of the Maine Drug Return Implementation Group and printing a report in fiscal year 2004-05.

| Other Special Revenue Funds | 2003-04 | 2004-05 |
|------------------------------------|----------------|----------------|
| Personal Services | \$0 | \$660 |
| All Other | 0 | 2,200 |
| Other Special Revenue Funds Total | <hr/> \$0 | <hr/> \$2,860 |

Sec. 4. Effective date. That section of this Act that enacts the Maine Revised Statutes, Title 22, chapter 604 takes effect July 1, 2005.

APPENDIX B

Membership list, Maine Drug Return Implementation Group

Maine Drug Return Implementation Group
Public Law 2003, Chapter 679
Friday, March 3, 2005

Appointment(s) by the President

| | |
|----------------------------|--|
| Sen. John L. Martin | Member of the Senate |
| Mr. Douglas Carr | Representing Pharmacies |
| Chief James Toman | Representing Local Municipal Enforcement Agencies |

Appointment(s) by the Speaker

| | |
|---------------------------------|--|
| Rep. William M. Earle | Member of the House |
| Rep. Susanne P. Ketterer | Member of the House |
| Katherine Bilotas | Representing Pharmaceutical Manufacturers |
| Stevan Gressitt, MD | Representing a Statewide Association of Medical Professionals |

Director, Maine Drug Enforcement Agency
Roy Mckinney, Director

Designee of Attorney General
James Cameron, Assistant Attorney General

Designee of Commissioner, Department of Environmental Protection
Ann Pistell, Environmental Specialist

Designee of Commissioner, Department of Human Services
Sally-Lou Patterson, Director

Staff:

Jane Orbeton 287-1670
OPLA
Jane.Orbeton@legislature.maine.gov

Danielle Fox 287-1670
OPLA
Danielle.Fox@legislature.maine.gov

APPENDIX C

Chart of Options for Drug Return Programs

Disposal of Unused Pharmaceuticals
Options Chart, January 28, 2005
*** Indicates a product stewardship model**

| Voluntary Drug Turn-in | |
|---|---|
| Without product stewardship | With product stewardship* |
| | Manufacturers file plan for approval with MDEP, MDEA |
| MDEA adopt rules | Same |
| Community sponsor | Same |
| Law enforcement receives drugs | Same |
| Statistical sampling of drugs identified and recorded | Same |
| Law enforcement disposes of drugs as required by state and federal law. May ship to consolidator for later disposal. | Same |
| Law enforcement reports results to MDEA | Same |
| Education and outreach by AG, MDEA, MDEP, Me Medical Assoc., Me Hospital Assoc., DHHS within their resources | Same parties provide education and outreach, plus manufacturers |
| State funding not required | Funding from manufacturers |
| Funding from other sources optional | Funding from other sources optional |
| Start date not needed | Start date 7/1/07 |
| | |
| Mail-in program | |
| Without product stewardship | With product stewardship* |
| | Manufacturers file plan for approval with MDEP, MDEA |
| MDEA adopt rules | Same |
| MDEA sponsors | MDEA or manufacturers sponsor |
| Mailers distributed to hospitals, pharmacies, physicians' offices, health centers. Program funds mailers and mailing costs. | Same procedures. Manufacturers pay for mailers and mailing. |
| Consumer mails to MDEA or to consolidation facility under contract with MDEA for disposal as hazardous waste. Statistical sample identified for recording and reporting. Program funds sampling and disposal costs. | Same procedures. Manufacturers fund sampling and disposal. |
| MDEA reports results | Manufacturers report results to MDEA |
| Education and outreach by AG, MDEA, MDEP, Me Medical Assoc., Me Hospital Assoc., DHHS within their resources and as funded by program | Same procedures with participation of manufacturers. Manufacturers fund education and outreach. |
| Funding needed, private and non-General Fund public funding. | Funding by manufacturers, other sources optional. |
| Enforcement by AG | Same |
| Start date 7/1/05 | Start date 7/1/07 |

APPENDIX D

Origins and Fate of PPCPs in the Environment

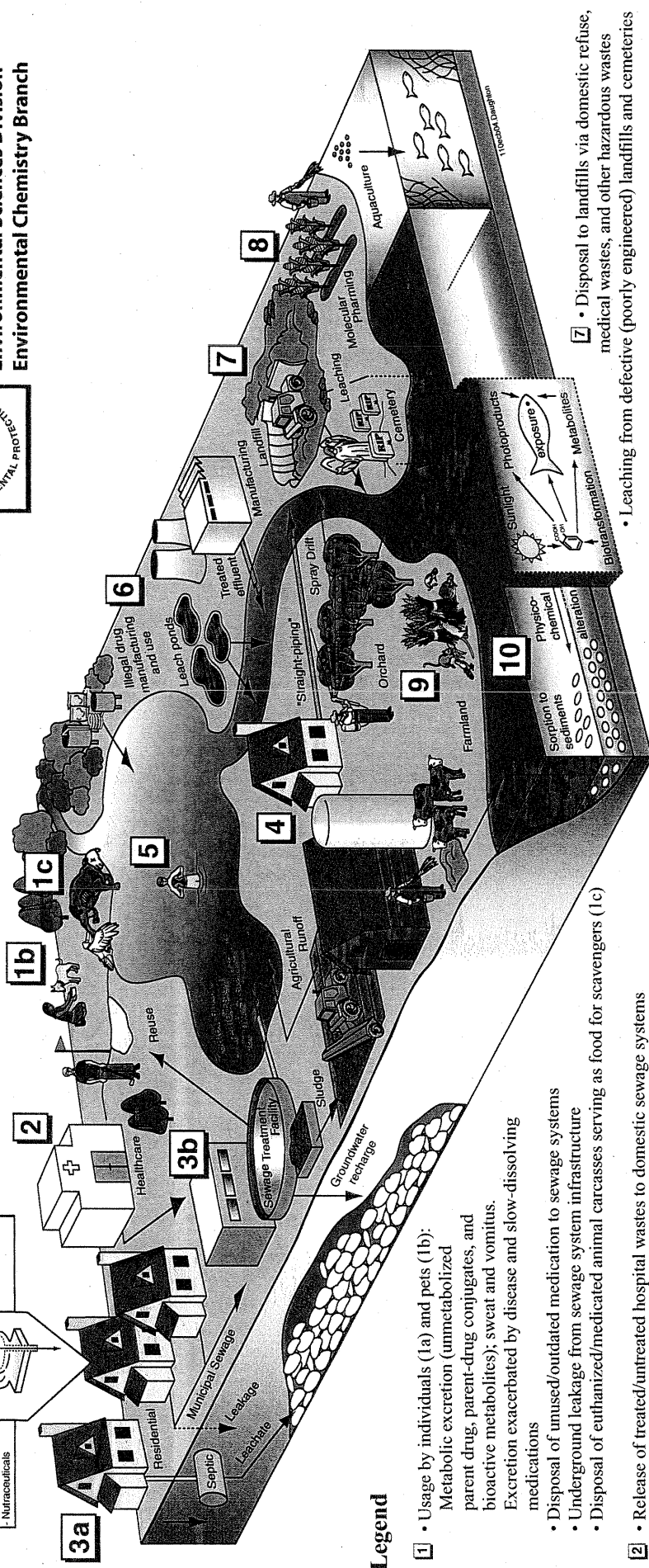
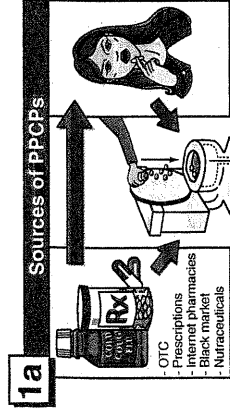
By Christian G. Daughton

<http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf>

Origins and Fate of PPCPs[†] in the Environment

Pharmaceuticals and Personal Care Products

U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Environmental Chemistry Branch



Legend

- 1 • Usage by individuals (1a) and pets (1b):
Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites); sweat and vomitus. Excretion exacerbated by disease and slow-dissolving medications
- 2 • Disposal of unused/outdated medication to sewage systems
- 3 • Underground leakage from sewage system infrastructure
- 4 • Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)
- 5 • Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus
- 6 • Release to private septic/leach fields
- 7 • Treated effluent from domestic sewage treatment plants discharged to surface waters or re-injected into aquifers (recharge)
- 8 • Overflow of untreated sewage from storm events and system failures directly to surface waters
- 9 • Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fertilization)
- 10 • "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
- 11 • Release from agriculture: spray drift from tree crops (e.g., antibiotics)
- 12 • Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)
- 13 • Direct release to open waters via washing/bathing/swimming
- 14 • Discharge of regulated/controlled industrial manufacturing waste streams
- 15 • Disposal/release from clandestine drug labs and illicit drug usage
- 16 • Release of drugs that serve double duty as pest control agents:
examples: 4-aminopyridine, experimental multiple sclerosis drug → used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antilipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → *coqui* frog control
- 17 • Disposal to landfills via domestic refuse, medical wastes, and other hazardous wastes
- 18 • Leaching from defective (poorly engineered) landfills and cemeteries
- 19 • Release to open waters from aquaculture (medicated feed and resulting excreta)
- 20 • Future potential for release from molecular pharming (production of therapeutics in crops)
- 21 • Phototransformation (both direct and indirect reactions via UV light)
- 22 • Physicochemical alteration, degradation, and ultimate mineralization
- 23 • Volatilization (mainly certain anesthetics, fragrances)
- 24 • Some uptake by plants
- 25 • Respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)
- 26 • Ultimate environmental transport/fate:
• most PPCPs eventually transported from terrestrial domain to aqueous domain
- 27 • Phototransformation (both direct and indirect reactions via UV light)
- 28 • Physicochemical alteration, degradation, and ultimate mineralization
- 29 • Volatilization (mainly certain anesthetics, fragrances)
- 30 • Some uptake by plants
- 31 • Respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

APPENDIX E

An Act Regarding the Unneeded Pharmaceutical Disposal Program

Draft

Legislation extending mail-in program start date 1 year and allowing acceptance of federal and nonfederal grant funding

File: G:\2004 Studies\Drug Return\extend start date.doc

Date: January 28, 2005

Title: An Act Regarding the Unused Pharmaceutical Disposal Program

Sec. 1. 22 MRSA §2700, subsection 5 is amended to read:

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund, ~~nonpublic fund~~ source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter.

Sec. 2. Public Law 2003, Chapter 679, section 4 is amended to read:

Sec. 4. Effective date. That section of this Act that enacts the Maine Revised Statutes, Title 22, chapter 604 takes effect July 1, ~~2005~~ 2006.

SUMMARY

This bill allows the acceptance into the Unused Pharmaceutical Disposal Program fund of public funds that are not General Fund funds and extends the beginning date from July 1, 2005 to July 1, 2006.

APPENDIX F

An Act to Establish the Unneeded Prescription Drug Redistribution Program

Title: An Act to Establish the Unused Prescription Drug Redistribution Program

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §254-C is enacted to read:

§254-C. Unused prescription drug redistribution program

There is established within the department the unused prescription drug redistribution program, referred to in this section as “the program,” to make prescription drugs available to low-income persons.

1. Collaboration. The department shall work collaboratively with hospitals, health clinics and federally qualified, Indian Health Service-sponsored and rural health centers to make prescription drugs available to qualified persons through the program.

2. Qualified persons. An individual is a qualified person if that individual meets the eligibility criteria set forth in this subsection.

A. An individual must have family income below 350% of the federal nonfarm income official poverty level, as defined by the federal Office of Management and Budget and revised annually in accordance with the United States Omnibus Budget Reconciliation Act of 1981, Section 673, Subsection 2.

B. An individual must be a legal resident of the State.

C. An individual must have a valid prescription for the drug to be dispensed through the program.

D. An individual may not receive MaineCare prescription drug benefits.

3. Accepting unused prescription drugs. The program may accept unused prescription drugs from drug manufacturers, drug wholesale or terminal distributors, hospitals, health clinics, federally qualified and rural health centers, nursing facilities and assisted living facilities licensed by the department as provided in this paragraph.

A. The program may accept unused prescription drugs that are unopened and packaged in tamper-evident unit dose packages or that are unopened injectable, aerosol or topical medications.

B. The program may accept unused prescription drugs from an entity donating under this subsection if:

(1) The entity is the owner of the prescription drug; or

(2) The entity has maintained custody of the prescription drug for an individual and donation of the prescription drug is accompanied by signed consent to the donation from the individual or authorized representative of the individual.

C. The program may accept unused prescription drugs that are controlled substances as defined by 21 Code of Federal Regulations, Part 1308 and regulations adopted by the federal Department of Justice, Drug Enforcement Administration as allowed by federal law and regulation.

D. The program may not accept unused prescription drugs that have been opened, tampered with or compromised in any way, that have not been stored as directed by the manufacturer, that are within 6 months of their expiration date or that have been held in the custody of the person to whom the prescription drug was originally dispensed.

4. Dispensing donated prescription drugs. The program shall dispense donated prescription drugs to qualified persons through hospitals, health clinics and federally qualified, Indian Health Service-sponsored and rural health centers, nursing facilities and assisted living facilities that volunteer to participate in the program. The program shall pay to the dispensing entity a dispensing fee equal to the dispensing fee provided under the MaineCare program.

5. Fees. To support the program the department may charge nominal fees as provided in this subsection.

A. The department may charge fees to entities making donations of unused prescription drugs under subsection 3.

B. The department may charge fees to persons to whom prescription drugs are dispensed under the program. A fee charged under this paragraph may not exceed the co-payment charged for a similar prescription drug under the MaineCare program.

6. Immunity. A drug manufacturer, drug wholesale or terminal distributor, hospital, health clinic, federally qualified, Indian Health Service-sponsored or rural health center, nursing facility or assisted living facility that makes a donation under subsection 3 or dispenses drugs under subsection 4 is immune from civil or criminal liability for the act of donating or the consequences of the donation or the act of dispensing.

7. Rulemaking. The department, after collaboration with the Maine Board of Pharmacy and the Maine Drug Enforcement Agency, shall adopt rules to implement the program. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill establishes the unused prescription drug redistribution program under which unused prescription drugs are accepted and dispensed to low-income persons. To be eligible for the program a person must have family income below 350% of the federal poverty level, must not receive MaineCare prescription drug benefits, must be a Maine resident and must have a valid prescription for the drug to be dispensed. The program may accept unused and unopened prescription drugs from drug manufacturers, drug wholesale and terminal distributors, hospitals, health clinics, federally qualified and rural health centers, nursing facilities and assisted living facilities licensed by the Department of Health and Human Services. The bill provides civil and criminal immunity for an entity making a donation to the program. The bill directs the Department of Health and Human Services to adopt implementing rules, designated as routine technical rules, after consultation with the Maine Board of Pharmacy and the Maine Drug Enforcement Agency.



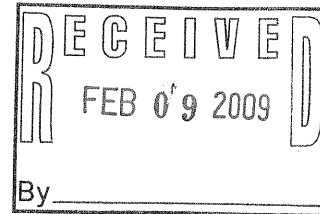
U. S. Department of Justice
Drug Enforcement Administration
New England Field Division
JFK Federal Building
15 New Sudbury Street, Room E-400
Boston, MA 02203

www.dea.gov

State of Maine, Department of Public Safety
Maine Drug Enforcement Agency
166 State House Station
Augusta, Maine 04333-0166

Dear Director McKinney:

FEB - 3 2009



On January 6, 2009, you sent a letter to the Drug Enforcement Administration (DEA), New England Field Division, regarding your proposed method for the collection of unwanted controlled substances from members of the public for the purpose of disposing of such controlled substances.

As set forth in 21 CFR 1307.21, any person in possession of a controlled substance, and desiring to dispose of such substance, may request instructions on how to do so from the Special Agent in Charge of that geographical region. As this provision of the DEA regulations indicates, the Special Agent in Charge may specify the means of disposal to assure that the controlled substances do not become available to unauthorized persons. Your letter will be treated as a request submitted pursuant to section 1307.21, and the request is hereby granted under the conditions enumerated below.

Please note the following general considerations for DEA in responding to this request. First, as you might know, DEA is currently in the process of developing regulations that will specify methods by which ultimate users may dispose of unwanted controlled substances. However, it is uncertain at this time when such regulations will become effective. Accordingly, any allowance made under this letter should be viewed as a temporary, interim accommodation to allow appropriate methods of disposal of controlled substances, where members of law enforcement take an active role in the process to prevent the controlled substances from being diverted into illicit channels. For this reason, a time limit is being imposed on the allowances made by this letter, as set forth below. Second, please bear in mind that any activities involving controlled substances, and any DEA regulations or temporary allowances made by the agency, must be consistent with DEA's governing statute, the Controlled Substances Act.

With the foregoing considerations in mind, you may proceed with the method of collection and disposal described in your January 6, 2009 letter, provided compliance with the following additional conditions. To the extent any of the conditions described in your letter are inconsistent with those specified below, the following shall apply in lieu of those set forth in your letter.

1. In each instance in which a controlled substance is collected, a duly authorized and certified law enforcement officer, who is a full-time employee of the Maine Drug Enforcement Agency (MDEA), shall be responsible for supervising the collection. If necessary, another duly authorized and certified law enforcement officer may be substituted for the first officer during the course of the event.
2. Starting when any controlled substances are first collected and continuing until the controlled substances are turned over for destruction (as set forth below in paragraph #4), the following shall occur: (a) the law enforcement officer referred to in paragraph #1 shall, at all times, have sole control over, and sole possession of, all controlled substances collected and the container, if any, in which the collected controlled substances are stored; and (b) at no time shall anyone other than the law enforcement officer referred to in paragraph #1 have access to the container or the collected controlled substances other than for the purpose of depositing controlled substances into the box.
3. Only pharmaceutical drugs may be collected and stored in the container designated as the storage location. Illicitly manufactured controlled substances (e.g. marijuana, heroin, methamphetamine, MIDMA, and LSD) may not be collected as part of this program. In the event a person seeks to turn in an illicitly manufactured controlled substance, the law enforcement officer shall follow the standard procedures implemented by his/her agency for the collection and handling of illegal controlled substances.
4. The law enforcement officer referred to in paragraph #1 shall be responsible for ensuring that the controlled substances are turned over to the appropriate officials within his/her agency for disposal in accordance with standard policies and procedures utilized by the agency for destruction of controlled substances.
5. Any methods utilized by the agency to destroy the collected controlled substances must comply with all applicable federal and state laws and regulations, including, but not limited to, applicable laws and regulations relating to public health and the environment.
6. The allowances made by this letter shall terminate on February 4, 2010, and may not be extended beyond that date without the express, written authorization of the Special Agent in Charge of the New England Field Division.

The DEA thanks the MDEA for its interest in and proactive approach to the safe and legal disposal of pharmaceutical controlled substances. This innovative project could potentially be a model to be used by other states. We are pleased to be a part of this important endeavor led by the MDEA, the US Postal Service, and the University of Maine's Center on Aging. If you have any further questions or concerns please do not hesitate to contact Diversion Program Manager Nancy Coffey at 617/557-2130.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Steven W. Derr". The signature is fluid and cursive, with a prominent "S" and "D".

Steven W. Derr
Special Agent in Charge
New England Field Division

Enclosure

MANAGER
MAILING STANDARDS



To: Maine Drug Enforcement Agency

Re: Establishing Operational Test Requirements for Mailing Unwanted or Unused Pharmaceuticals, Including Controlled Substances, for Disposal

Purpose: By this letter, you (Maine Drug Enforcement Agency or "MDEA") are authorized to participate in an operational test of the mailing of unwanted or unused pharmaceuticals, including controlled substances, for disposal.

Background: Current postal statutes and regulations generally permit the mailing of controlled substances, drugs that contain controlled substances, and drugs other than controlled substances, to the extent that the distribution of these drugs is lawful under the Controlled Substances Act ("CSA"), codified in 21 U.S.C. § 801 *et seq.* and 21 C.F.R. § 1300 *et seq.*, applicable regulations of the Food and Drug Administration ("FDA"), and all applicable federal, state, and local laws, provided that either (1) the mailer is registered with the Drug Enforcement Agency ("DEA"), or (2) the mailer is exempt from DEA registration. See Domestic Mail Manual ("DMM") § 601.11.11. Postal regulations provide that mailers must use Merchandise Return Service for the return of prescription drugs for the purposes of drug recalls, voluntary manufacturer withdrawals, and dispensing errors, in accordance with DMM § 601.11.11.5. Federal and postal statutes and regulations generally prohibit consumers from mailing prescription drugs and controlled substances.

The Postal Service understands that MDEA proposes to participate in a pilot program whereby MDEA will provide consumers with mailing containers and envelopes, approved by the United States Postal Service ("USPS" or "Postal Service"), for the purpose of mailing unwanted or unused pharmaceuticals for disposal by MDEA. These mailing containers and envelopes will be distributed to consumers at pharmacies participating in the pilot program. For each mailing container or envelope distributed to a consumer, MDEA will ensure that a merchandise return label is printed on the mailing container or envelope that will be distributed to the consumer.

The Postal Service further understands that MDEA intends to establish a post office box for the receipt of unwanted or unused pharmaceuticals approved for mailing under this operational test agreement and that MDEA will oversee the collection and disposal of the unwanted or unused pharmaceuticals delivered to that post office box.

The Postal Service further understands that MDEA will be working in conjunction with the University of Maine Center on Aging to effectuate this operational test. The Postal Service acknowledges that both entities are concerned that the presence of unwanted or unused pharmaceuticals in the households or residences of consumers may facilitate the potential misuse or abuse of such pharmaceuticals. The Postal Service also acknowledges that both entities are concerned that certain existing methods used by consumers to dispose such pharmaceuticals (e.g., disposal via the trash or municipal sewer system) may have adverse effects on the environment.

Pursuant to the terms and conditions of this operational test agreement, set forth herein, the Postal Service hereby authorizes MDEA to provide approved mailing containers and envelopes with Merchandise Return Service to consumers for the purpose of mailing unwanted or unused pharmaceuticals for disposal.

Legal Authority: The Postal Service's authority to permit MDEA to participate in this operational test is provided by 39 U.S.C. §§ 401 and 404(a); 18 U.S.C. §§ 1716(b) and 1716(d).

Obligations of MDEA:

MDEA ("Mailer") hereby agrees to:

1. comply with all applicable federal statutes and regulations, including all applicable DEA and FDA regulations;
2. ensure that all padded mailing envelopes or containers distributed to consumers for the mailing of unwanted or unused pharmaceuticals authorized to be mailed under this operational test agreement are approved by the Postal Service and meet the packaging requirements in DMM § 601.11.11.4;
3. establish a post office box in accordance with all applicable requirements in DMM § 508.4 for the receipt of mailings authorized by this operational test and provide the address of this box to the Manager of Mailing Standards;
4. use Merchandise Return Service with First-Class Mail or Priority Mail in accordance with all applicable requirements in DMM § 507.10 for all mailings authorized by this operational test agreement, and for each mailing, distribute an approved merchandise return label directly onto the approved mailing container in accordance with all applicable requirements in DMM § 507.10.5;
5. provide a step-by-step instruction sheet with each mailing container or envelope that clearly states that:
 - a. pharmaceuticals must be in their original containers when placed into the provided envelope or container;
 - b. no more than four (4) ounces of liquid pharmaceuticals may be included in each mailing and that each original container holding a liquid pharmaceutical must be wrapped in a paper towel and placed in a sealed plastic bag (e.g., a zip-locked bag) before being placed in the provided mailing container or envelope;
 - c. syringes or sharps may not be mailed;
 - d. customers should call the customer service telephone number if they have questions regarding packaging requirements; and
 - e. the procedures customers must follow when calling the customer service telephone number if customers have questions prior to the time of mailing; and
6. identify to the Manager of Mailing Standards, the name, address, and phone number of the MDEA collection site that will receive mailings authorized by this operational test agreement. (Information provided in accordance with this subparagraph 6 will not be printed on the mailing container or released to the public except in accordance with the Confidentiality and Disclosure paragraph below.)

Term of Agreement: The operational test will commence on April 1, 2008, and is scheduled to expire on April 1, 2010.

Mailer's Warranty: Mailer warrants and represents that it is authorized to mail, collect, dispose, or otherwise handle pharmaceuticals, including controlled substances, under applicable federal statutes and regulations, including all applicable DEA and FDA regulations.

Confidentiality and Disclosure: The Postal Service may disclose information relating to this operational test if such information is requested by any federal, state, or local governmental body in the proper exercise of its oversight or investigatory jurisdiction. The Postal Service may also disclose information relating to this operational test if such release is required by the Freedom of Information Act (5 U.S.C. § 552), the Postal Regulatory Commission under the Rules of Practice and Procedure of the Postal Regulatory Commission (39 C.F.R. § 3001 *et seq.*), or in accordance with legal process under the rules of any court of competent jurisdiction. Additionally, the Postal Service reserves the right to use its

evaluation and the results of the operational test as a basis for future rulemaking. Upon request, Mailer agrees to disclose internal data on the results of the operational test to the Postal Service.

Suspension or Revocation of Mailer Authorization: Authorization to participate in this operational test is contingent upon compliance with all criteria, requirements, and terms and conditions stated herein, the requirements of the DEA and FDA, and all other federal and state statutes and regulations. Mailer understands and agrees that the Postal Service may suspend or revoke its authorization for any mailing under this operational test if the Postal Service determines, in its sole discretion, that the mailing does not meet the requirements of this operational test agreement or for any other reason, including, but not limited to: (1) an order, ruling, letter, electronic message, or any other communication issued by the DEA indicating that this operational test, in whole or in part, is contrary to, or inconsistent with, the CSA, or (2) an order, ruling, letter, electronic message, or any other communication issued by the DEA or the FDA indicating that this operational test, in whole or in part, is contrary to, or inconsistent with, any regulation promulgated by the DEA or the FDA, or any applicable federal law.

The Postal Service's decision to suspend or revoke Mailer's authorization may be communicated to Mailer by telephone, in writing, or by electronic message. The decision will be effective immediately, the mailings subject to this authorization will become nonmailable immediately, and the distribution of mailing envelopes or containers pursuant to this operational test will cease. Mailer may contest the Postal Service's decision to suspend or revoke its authorization by writing to the Manager, Mailing Standards (Mailing Standards, US Postal Service, 475 L'Enfant Plz., SW, Room 3436, Washington, D.C. 20260-3436), within 7 days of receipt of the Postal Service's decision or communication. The appeal should provide evidence demonstrating why the decision should be reconsidered. Any order suspending or revoking authorization remains in effect during an appeal or other challenge.

Limitation of Liability: MDEA understands and acknowledges that under no circumstances, including but not limited to negligence, shall the Postal Service be held liable for any damages including, without limitation, actual, special, indirect, incidental, punitive, consequential or any other damages (including, without limitation, damages for loss of business profits, business interruption or any other loss), or for costs incurred by either party, including, but not limited to attorney's fees, that arise from, are caused by, or are proximately caused by either (1) Mailer's participation in this operational test or (2) suspension or revocation of any authorization granted by this operational test agreement. MDEA understands and acknowledges that it may not apply to a court for any equitable remedy, including without limitation, specific performance and/or injunctive relief, in order to enforce this operational test agreement or any provision herein in the event of suspension or revocation of any authorization granted under this operational test.

Indemnification: To the extent permitted by law, Mailer shall hold harmless and indemnify the Postal Service and the United States of America and their employees, officers, agents, and representatives from all claims; losses; damages; actions; causes of action; expenses of any kind, including legal expenses; and/or liability resulting from, brought for, or on account of any personal injury, illness, death, or damage to property, or claim for contract damages or any other equitable relief, claimed, received or sustained by any person, persons or property growing out of or related to Mailer's participation in the operational test, except if due to the negligent or wrongful act or omission by any employee of the Postal Service while acting within the scope of his or her employment under circumstances where the Postal Service would be held liable in the same manner and to the same extent as a private individual under like circumstances.

Non-Exclusivity: The Postal Service reserves the right to allow other mailers to participate in similar operational tests.

Regulatory Action: Upon evaluation of the operational test, the Postal Service, in its sole discretion, will determine whether or not to amend or revise its regulations on mailability.

Point of Contact: All communications regarding this operational test will be referred to Roy E. McKinney, Director, Maine Drug Enforcement Agency.

Please acknowledge below that you agree to comply with terms of this operational test. Failure to acknowledge compliance will lead to the withdrawal of this authorization letter.



3-24-08

Sharon Daniel
Manager
Mailing Standards

Acknowledgement: I have reviewed the terms of this operational test and agree to comply with them.



3-20-08

(Roy McKinney)
Director, Maine Drug Enforcement Agency

**Northern New England Poison Center
Medication Disposal Summary Report**
Latest update (1/17/2008)

Purpose

The purpose of this report is to:

- Summarize research related to, and the controversy surrounding, medication disposal.
- Document rationale for the Northern New England Poison Center's (NNEPC) Medication Disposal Recommendation.

Executive Summary

Medication-related overdoses have increased significantly in recent years.¹ Limiting access to medicines is a key prevention strategy ("clean out the medicine cabinet").²

Pharmaceuticals and other personal care products (PPCP) have been found in our water supply.³ The sources are most likely excrement, flushed products and ground water contamination from land-fills.^{4, 5, 6, 7} The presence of PPCP in the environment has not been proven to negatively affect humans. However, the health effects from long-term exposure to these compounds are not clear.⁸

There is controversy about how to properly dispose of medicines (Table 1 & 2).⁹ There are three common methods utilized throughout the United States for medication disposal: flushing, throwing away and collecting.^{5,10,11} All of these options have strengths and weaknesses. Legislation related to medication reuse and disposal varies by state. The goal of any disposal method needs to keep these in mind:

- Prevent acute poisoning;
- Prevent abuse;
- Ensure patient safety;
- Limit environmental impact and water supply contamination.

Ultimately, any disposal recommendation needs to be practical, cost effective and safe. The NNEPC is taking an active role in developing disposal recommendations for the general public and health care and public health professionals.

Call to Action

In 2006 the American Medical Association (AMA) passed a resolution asking the United States Environmental Protection Agency (EPA) to lead the nation in addressing this issue. The AMA requested that the EPA:

1. Continue aggressive research to understand the public health impact of PPCP's on the drinking water supply, environment and human health.
2. Lead and engage stakeholders from other federal agencies, the pharmaceutical industry, hospitals and other health care institutions, health professional organizations representing physicians, pharmacists, and nurses and the public for the proper disposal of PPCP to prevent drinking water contamination and environmental impact.¹²

Medicine-Related Poisonings

Childhood poisonings - In 2005, in the United States, more than a half-million calls were made to poison centers about medication-related poisonings among children 5 years of age and younger.¹³

Medication overdoses - In 2004, poisoning became the second leading cause of death from unintentional injury in the United States. According to the Centers for Disease Control and Prevention, nearly all poisoning deaths in the United States are attributed to drugs, and most drug poisonings result from the abuse of prescription or illegal drugs.¹ Several reports confirm this alarming trend of pharmaceutical abuse and misuse.^{14,15,16,17,18}

Pharmaceuticals and Personal Care Products (PPCP) in the Water Supply

Medicines are not entirely absorbed by our bodies, and are excreted and passed into wastewater and surface water. According to the Environmental Protection Agency, studies have shown that pharmaceuticals are present in our nation's waterbodies.³⁻⁷ Research suggests that certain drugs may cause harm to the environment. To date, scientists have not found evidence of adverse human health effects from PPCP's in the environment.⁸

Medications' effects on the aquatic environment:

- Ability to resist degradation in the aquatic environment;
- Accumulation in adipose tissue of aquatic organisms;
- Potential to poison aquatic organisms.¹⁹

It is important to remember, "Not everything that counts can be counted and not everything that can be counted counts." – *Albert Einstein*²⁰

Medication Disposal Recommendations

There is no undisputed recommendation for disposing of medicines (Table 1 & 2). There are three common methods utilized throughout the United States for medication disposal: flushing, throwing away and collecting for incineration. Community-based studies show that most people dispose of unwanted medicines in their garbage or by flushing them down their toilets or sinks, but would be willing and interested in properly disposing of their unused or expired medicines by returning them to a convenient location (such as a pharmacy).^{5, 9-11,21,22}

Table 1. Comparison of Medication Disposal Recommendations

| Strength | Take-back incineration programs | Pharmacy take-back programs | Hazardous waste management | Throwing away medicines in the garbage | Flushing medicine down the sink or toilet |
|---|--|------------------------------------|-----------------------------------|---|--|
| Prevents children and pets from unintentional poisonings | √ | √ | √ | | √ |
| Prevents drug users access to medicines | √ | √ | √ | | √ |
| Low impact on the environment | √ | | | | |
| Relatively inexpensive for the participants and communities | | | | √ | √ |
| Population in support | √ | √ | √ | | |
| Convenient | | | | √ | √ |
| Weakness | Take-back incineration programs | Pharmacy take-back programs | Hazardous waste management | Throwing away medicines in the garbage | Flushing medicine down the sink or toilet |
| Costly | √ | √ | √ | | |
| Inconvenient for participants | √ | √ | √ | | |
| Not available in all communities | √ | √ | √ | | |
| Where available, it is infrequent and may lead to hoarding (e.g., storing of medicines for once a year disposal could lead to poisonings or drug diversion) | √ | | √ | | |
| Inconsistent disposal practices among pharmacies | | √** | | | |
| Potential risk of unintentional poisonings of children and pets | | | | √ | |
| Potential risk of access to medicines for drug users | | | | √ | |
| Increases the amount of medication in our water supply and environment | | √** | √** | √** | √ |
| Not allowed to accept controlled substances | √^ | √^ | √ | | |

** This may lead to an increase in the water supply, depending on how material is discarded.

^ Depends on state laws and regulations.

Table 2. Various Agency Recommendations

| Federal Agency | Medication Disposal Recommendation | Website |
|---|---|--|
| American Pharmacists Association | <p>Crush solid medications or dissolve them in water (this applies for liquid medications as well) and mix with kitty litter or sawdust (or any material that absorbs the dissolved medication and makes it less appealing for pets or children to eat), then place in a sealed plastic bag BEFORE tossing in the trash.</p> <p>Remove and destroy ALL identifying personal information (prescription label) from the medication container.</p> <p>Check for approved state and local collection programs or with area hazardous waste facilities. In certain states, you may be able to take your unused medications to your community pharmacy.</p> | http://www.pharmacist.com/AM/Template.cfm?Section=Public_Health2&Template=/CM/HTMLDisplay.cfm&ContentID=11650 |
| US Fish and Wildlife Services | | |
| Environmental Protection Agency | <ul style="list-style-type: none"> ▪ Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash. ▪ Mix prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted. ▪ Flush prescription drugs down the toilet <i>only</i> if the label or accompanying patient information specifically instructs doing so. ▪ Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals. | http://whitehousedrugpolicy.gov/drugfact/factsheet/proper_disposal.html http://jama.ama-assn.org/cgi/content/full/297/12/1307-a |
| Department of Health and Human Services | | |
| American Medical Association | | |
| Office of National Drug Control Policy | | |
| Substance Abuse and Mental Health Services Administration | <ul style="list-style-type: none"> • Mix unused drugs with coffee grounds, kitty litter, or another undesirable substance and place in a sealed container before disposing in the trash. • Prescription drugs should not be flushed down the toilet unless specifically instructed to do so. • Where community prescription drug take-back programs exist, they are a good way to dispose of unused pharmaceuticals. | http://www.samhsa.gov/rxsafety/SAMHSA3tagged.pdf |
| Food and Drug Administration | Throw away expired medicines at a home hazardous waste disposal site or in a garbage can away from small children and pets. | http://www.fda.gov/medsinmyhome/MIMH_as_they_grow.htm |
| Centers for Disease Control | Return to the pharmacy | http://www2a.cdc.gov/podcasts/media/pdf/EID%20Podcast%2010-18-06%20Antimicrobials%20Transcript.pdf |

| | | |
|--|--------------|--|
| American Association of Poison Control Centers | Under review | www.aapcc.org |
|--|--------------|--|

Continue Table 2.

| State Agency | Medication Disposal Recommendation | Website |
|--|--|---|
| Maine Department of Environmental Services | A. Voluntary Turn-In Events B. Mail-In Program C. Product Stewardship D. Legislation to Consider Redistribution | http://www.umaine.edu/mainecenteronaging/documents/globalperspectives.pdf |
| Maine Department of Health and Human Services | | |
| Maine Pharmacy Association | Under review | www.mparx.com |

| | | |
|---|--|---|
| New Hampshire Department of Environmental Services | <p>Contact your local household hazardous waste coordinator prior to a collection event to determine if your municipality will accept the waste. Most collection events will accept mercury-added or other personal care products, but not pharmaceutical waste.</p> <p>Dispose of the waste in household trash.</p> <p>Keep products in their original containers. Pharmaceutical container caps are typically watertight and child proof.</p> <p>Add a small amount of water to a solid drug or some absorbent material such as kitty litter, sawdust or flour, to liquid drugs before recapping to discourage any unintended use of the drug.</p> <p>Double seal the container in another container or heavy bag to prevent easy identification of the drug container</p> | http://www.des.state.nh.us/factsheets/sw/sw-33.htm |
| New Hampshire Department of Health and Human Services | <p>Crush solid medications or dissolve them in water (this applies for liquid medications as well) and mix with kitty litter or sawdust (or any material that absorbs the dissolved medication and makes it less appealing for pets or children to eat), then place in a sealed plastic bag BEFORE tossing in the trash.</p> <p>Remove and destroy ALL identifying personal information (prescription label) from the medication container.</p> | http://whitehouse.gov/press07/022007.html |
| New Hampshire Pharmacy Association | | |

| | | |
|---------------------------------|--|---|
| Vermont Department of Health | <ul style="list-style-type: none"> Take unused, unneeded or expired prescription and over-the-counter drugs out of their original containers. Mix the prescription drugs with an undesirable substance (for example, used kitty litter, coffee grounds, bacon fat, soil), place the mixture into a | http://healthvermont.gov/adap/adap.aspx |
|---------------------------------|--|---|

| | | |
|------------------------------|---|--|
| | sealable plastic bag or container, and place it into the trash. <ul style="list-style-type: none"> • When discarding a transdermal patch, fold the patch into itself and then place it in the undesirable mixture. | |
| Vermont Pharmacy Association | Under review | www.vtpharmacists.org |

References

- ¹ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm>
- ² http://www.drugfree.org/Portal/DrugIssue/Research/Teens_2005/Generation_Rx_Study_Confirms_Abuse_of_Prescription
- ³ <http://www.epa.gov/ppcp/>
- ⁴ http://www.nesc.wvu.edu/nsfc/pdf/pipline/PL_wi07.pdf
- ⁵ Kuspis DA, Krenzelok EP. What happens to expired medications? A survey of community medication disposal. Vet Hum Toxicol. 1996 Feb;38(1):48-9.
- ⁶ <http://www.epa.gov/ppcp/pdf/drawing.pdf>
- ⁷ <http://www.epa.gov/ppcp/faq.html#sources>
- ⁸ <http://www.epa.gov/ppcp/faq.html#Insimpleterms>
- ⁹ <http://www.epa.gov/ppcp/faq.html#how>
- ¹⁰ <http://lists.dep.state.fl.us/pipermail/pharmwaste/2006-October/000665.html>
- ¹¹ <http://www.mainebenzo.org/documents/pharmacistslettervol23.pdf>
- ¹² <http://www.mainebenzo.org/documents/Sept.2006EPAletteronPPCPs.doc>
- ¹³ Table 22B. <http://www.aapcc.org/Annual%20Reports/06Report/2006%20Annual%20Report%20Final.pdf>
- ¹⁴ <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/methadone1999-04/methadone1999-04.htm>
- ¹⁵ <http://nmhealth.org/pdf/Drug%20Overdose%20Death%20in%20New%20Mexico%202006.pdf>
- ¹⁶ http://www.utexas.edu/research/cswr/gcattc/documents/PrescriptionTrends_Web.pdf
- ¹⁷ http://www.fda.gov/fdac/features/2001/501_drug.html
- ¹⁸ http://www.drugfree.org/Portal/DrugIssue/Research/Teens_2005/Generation_Rx_Study_Confirms_Abuse_of_Prescription
- ¹⁹ Community Medical Foundation for Patient Safety PowerPoint Presentation August 11, 2006, 12pm. Environmental Hazard and Pharmaceuticals: Some Insights of the Hazards. Presented by Ye Sun.
- ²⁰ <http://jpetrie.myweb.uga.edu/einstein.html>
- ²¹ Abahussain EA, Ball DE, Matowe WC. Practice and opinion towards disposal of unused medication in Kuwait. Med Pric Prac. 2006;15(5):352-7.
- ²² <http://www.ncsl.org/programs/health/drugbill07.htm>

The NNEPC is supported by: Maine Medical Center, a member of the MaineHealth Family; Maine Center for Disease Control and Prevention, Department of Health and Human Services; The United Way; New Hampshire Department of Safety; Vermont Department of Health; Fletcher Allen Health Care. The Northern New England Poison Center is also supported by funds received through grant #H4BHS00078-07-00 and #U4BHS08564-01-00, awarded by the Department of Health and Human Services, Health Resources and Services Administration. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Health Resources and Services Administration, Division of Healthcare Preparedness, Healthcare Systems Bureau.

Stevan Gressitt, M.D., Medical Director
 Office of Adult Mental Health Services
 Department of Health and Human Services
 Marquardt Building, 2nd Floor
 11 State House Station
 32 Blossom Lane
 Augusta, ME 04333-0011
 Ph: (207)287-4273
 Fax: (207)287-1022
 Cell Phone: (207) 441-0291
 E-Mail : stevan.gressitt@maine.gov
<http://www.maine.gov/dhhs/mh/>

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s). It may contain confidential and privileged information. Any unauthorized review, copy, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please note that any dissemination, distribution or copying of this is strictly prohibited. Please contact me by reply e-mail or telephone and destroy all copies of this message. The Department of Health and Human Services (DHHS) does not discriminate on the basis of disability, race, color, creed, gender, sexual orientation, age, or national origin, in admission to, access to, or operations of its programs, services, or activities, or its hiring or employment practices. This notice is provided as required by Title II of the Americans with Disabilities Act of 1990 and in accordance with the Civil Rights Act of 1964 as amended, Section 504 of the Rehabilitation Act of 1973, as amended, the Age Discrimination Act of 1975, Title IX of the Education Amendments of 1972 and the Maine Human Rights Act and Executive Order Regarding State of Maine Contracts for Services. Questions, concerns, complaints or requests for additional information regarding the ADA may be forwarded to DHHS' ADA Compliance/EEO Coordinators, 11 SHS-221 State Street, Augusta, Maine 04333, 207-287-4289 (V), 207-287-3488 (V), 1-800-606-0215 (TTY).

From: provider-bounces@informe.org [mailto:provider-bounces@informe.org] **On Behalf Of** Provider Notification
Sent: Friday, July 31, 2009 3:59 PM
To: List Serve
Subject: [Provider] 15-day limit on first-time prescriptions for certain drugs

MaineCare has begun instituting measures to ensure cost effectiveness through the use of Drug Benefit Management, Drug-Drug editing to ensure education and patient safety, recent PPI limitations and Intensive Benefit Management with controlled substances.

For a number of years in Maine, research from the Maine Benzodiazepine Study Group, The University of Maine Center on Aging, and in part funded by the only Federal Grant in the US on unused drug return mail back programming has suggested that adherence to medication and other variables may lead to large amounts of unused and discarded medication. Closer evaluation of side effects and efficacy may lead to better patient outcome and better safety for patients with closer evaluation of initial response.

With that, MaineCare will institute new 15 day limits on initial prescriptions for various medication that have been identified with high side effect profiles, high discontinuation rates, or frequent dose adjustments to ensure cost effectiveness without "wasting" or "discarding" of used medications. Effective 8/6/09 MaineCare will begin limiting initial prescriptions on the following medications, Suboxone, Subutex, Chantix and Nicotine replacement products to 15 day supplies. Initial prescriptions for preferred products over the initial 15 day supply will require prior authorization. Subsequent refills of these products will be allowed at the usual MaineCare allowable days supply.

For further questions please contact Goold Health Systems at 1-888-4450497.

Is your mailing address up to date with MaineCare? Please keep MaineCare up to date so your Remittance Statements and checks arrive on time. Call Provider Enrollment at 1-800-321-5557 Option #6.

If you would rather not get these e-mails, visit [MaineCare's List Serve Subscription](#) page to unsubscribe.

This is a one-way communication. Do not reply to this e-mail. Your e-mail will not receive response. If you have questions, please call 1-800-321-5557.



WHEREAS, unused and unwanted consumer pharmaceuticals have a negative impact on public health and the environment and the lack of effective and efficient methods of drug disposal has resulted in unwelcome social, cultural, ecological and global effects; and

WHEREAS, theft and social use, misuse, and abuse of pharmaceuticals by teenagers, adults and older adults has increased; and

WHEREAS, increasing poly-pharmacy, non-adherence to prescriptions and medication errors contributes to accumulation and poor patient outcomes; and

WHEREAS, potential deleterious effects on wildlife and humans due to drug disposition in surface and ground waters are a result of improper disposal; and

WHEREAS, unused medications represent wasted health care dollars to both consumers, insurance carriers and tax payers,

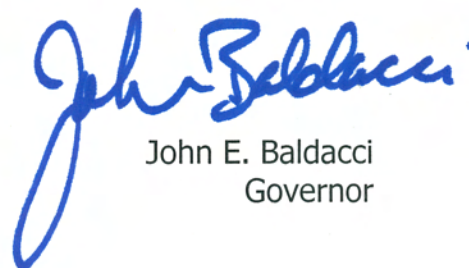
NOW, THEREFORE, I, JOHN E. BALDACCI, Governor of the State of Maine, do hereby proclaim October 31, 2007 as

PROPER DRUG DISPOSAL DAY

throughout the State of Maine, and urge all citizens to recognize the need for proper adherence to medication and appropriate drug disposal across the State of Maine.



In testimony whereof, I have caused the Great Seal of the State to be hereunto affixed GIVEN under my hand at Augusta this twenty-sixth day of October in the Year of our Lord Two Thousand and Seven.


John E. Baldacci
Governor


Matthew Dunlap
Secretary of State
TRUE ATTESTED COPY



WHEREAS, unused and unwanted consumer pharmaceuticals have a negative impact on public health and the environment and the lack of effective and efficient methods of drug disposal has resulted in unwelcome social, cultural, ecological and global effects; and

WHEREAS, theft and social use, misuse, and abuse of pharmaceuticals by teenagers, adults and older adults has increased; and

WHEREAS, increasing poly-pharmacy, non-adherence to prescriptions and medication errors contributes to accumulation and poor patient outcomes; and

WHEREAS, potential deleterious effects on wildlife and humans due to drug disposition in surface and ground waters are a result of improper disposal; and

WHEREAS, unused medications represent wasted health care dollars to both consumers, insurance carriers and tax payers,

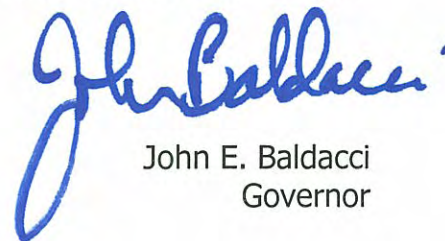
NOW, THEREFORE, I, JOHN E. BALDACCI, Governor of the State of Maine, do hereby proclaim October 31, 2008 as

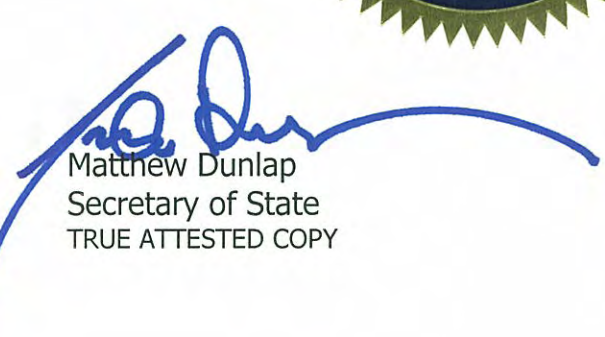
PROPER DRUG DISPOSAL DAY

throughout the State of Maine, and urge all citizens to recognize the need for proper adherence to medication and appropriate drug disposal across the State of Maine.

In testimony whereof, I have caused
the Great Seal of the State to be
hereunto affixed GIVEN under my
hand at Augusta this fifth
day of September in the Year of our
Lord Two Thousand and Eight.




John E. Baldacci
Governor


Matthew Dunlap
Secretary of State
TRUE ATTESTED COPY

THE ATHENS DECLARATION as unanimously voted on August 3rd, 2007 at the 2nd International Conference on Environment in the City of Athens Cultural Center is as follows:

We, an international group, support the following six reasons to address citizen unused drug disposal:

1. To curtail childhood overdoses
2. To restrict household drug theft
3. To limit accumulation of drugs by the elderly
4. To protect our physical environment
5. To restrain improper international drug donations
6. To eliminate waste in the international health care systems of all countries

We call upon governments, NGO's, and citizens everywhere to correct policies and practices that foster waste in the health care systems of all countries and endanger humans, animals, and our physical environment.

We call upon all countries to renew their support of WHO Guidelines on Drug Donations and the WHO Guidelines on Drug Disposal, and strive to improve on these.

We call upon health care providers worldwide to appropriately prescribe medicines to patients in the most effective form and quantity.

We call upon health care organizations to refrain from policies that promote excessive dispensing.

We call upon patients worldwide to recognize the need for medicine to be taken as intended if it is to be effective.

We call upon governments, NGO's, and citizens worldwide to refrain immediately from improper drug donations either as humanitarian aid following disasters or in general practice.

We call upon others to endorse these principles with us for the betterment of the health of the environment and patients worldwide.

**Athens,
Greece
August 3rd,
2007**



In North America:
Maine Benzodiazepine Study
Group
Stevan Gressitt, M.D.
207-441-0291
Gressitt@uninets.net
www.mainebenzo.org

Whereas inattention to prescribing policy, reimbursement incentives, formulary selection, distribution, pricing systems, dispensing and actual prescription writing, have led to the need for this Istanbul Statement of September 7, 2009 during the 69th Conference of FIP. Confirming the Athens Declaration of 2007, this Statement as well draws attention to responses to these problems in the Netherlands, Sweden, and the State of Maine in the United States of America. Research from a number of countries as diverse as Canada and Kuwait demonstrate the need for further work and research but already a need for addressing the problem.

We thereby ask that all NGO's, governmental bodies, health care professionals, pharmaceutical manufacturers, and citizens everywhere place unused drug disposal and prevention of pharmaceutical waste as a highest priority. We encourage those listed above to move to address this problem as soon as possible.

Istanbul, Turkey

September 7, 2009

Stevan Gressitt, M.D.

Rationale for a Concerted Focus on Unused Pharmaceuticals

Ilene S. Ruhoy, MD

Doctoral Candidate

University of Nevada, Las Vegas

Department of Environmental Studies

Stevan Gressitt, MD

Maine Benzodiazepine Study Group, The Drug Disposal Group,

Medical Director, Northeast Occupational Exchange,

Corresponding Author: 314 Clark Road, Unity, Maine, 04988 207-441-0291

gressitt@uninets.net

Abstract:

Unused and unwanted consumer pharmaceuticals have a negative impact on public health. The lack of effective and efficient methods of drug disposal has resulted in unwelcome social, cultural, ecological, and global effects.

Among the many issues pertinent to unused consumer medication, we have comprehensively explored and addressed six specific and significant problems;

- 1) **Childhood Poisoning:** Unintentional pharmaceutical poisonings of children, resulting in unnecessary morbidity and mortality.
- 2) **"Pharming":** Theft and social use, misuse, and abuse of pharmaceuticals by teenagers, adults, and older adults.
- 3) **Excessive Accumulation and Polypharmacy:** Polypharmacy, non-compliance and/or poor adherence to medication regimens, and medication errors contributes to accumulation and poor patient outcome.
- 4) **Unintended Environmental Exposure:** Potential deleterious effects on wildlife and humans due to drug deposition in surface and ground waters as a result of both disposal and excretion pathways.
- 5) **Inappropriate Humanitarian Drug Donations:** Under-regulated and poorly controlled methods of international donations to countries in need, resulting in massive amounts of "gifts" of unused and expired pharmaceuticals. Expired and unwanted drugs ultimately become accumulated waste, some of which may be hazardous, due in part to the lack of an environmentally sound disposal or destruction method.
- 6) **Pharmacoeconomics:** Unused medications contribute to wasted health care dollars. The purchase costs of drugs to the consumer, the insurance carrier, and the taxpayer have continued to increase in the past decade.

These issues define the problem of proper disposal of unused pharmaceuticals and beg for acceptable solutions to protect human and environmental health.



FOR IMMEDIATE RELEASE
April 8, 2010

POSTAL NEWS

Contact: Darlene Casey
(O) 202-268-3440
darlene.casey@usps.gov
usps.com/news
Release No. 10-032

Postal Service Expands Prescription Mail Back

Program Diverts Expired, Unused Medicine from Landfills, Water Supply

WASHINGTON — Veterans will be able to safely dispose of expired and unused prescriptions and help the environment at the same time under a program offered by the U.S. Postal Service and U.S. Department of Veterans Affairs (VA).

This pilot program is limited to an estimated 780,000 veterans living in Baltimore, Washington, DC, and West Virginia. Veterans mail back outdated, unwanted medicine. Federally approved facilities safely destroy the medicine, insuring that prescriptions don't end up in municipal refuse, soil or ground water.

"This initiative pairs the convenience of the mail with the safety of a federally approved prescription drug disposal process," said Robert Bernstock, president, Mailing and Shipping Services. "The Prescription Mail Back program demonstrates the Postal Service's continued value as an integral part of American communities."

Veterans receive specially designed, postage-paid envelopes and instructions with their prescription fulfillment. Expired and unused pharmaceuticals placed in the special packaging can be dropped in familiar blue USPS collection boxes or at Post Offices. The envelopes are delivered to facilities regulated and approved by the Environmental Protection Agency (EPA) and Drug Enforcement Agency (DEA). Pharmaceuticals from this and other similar mail-back initiatives are destroyed in accordance with EPA and DEA standards, including cataloging and use of incineration, chemical or thermal processes.

The prescription mail-back initiative began in the state of Maine in 2008, and has been successfully expanding ever since. The VA program joins similar ones in 47 states. Mail-back envelopes are being distributed at supermarket pharmacies, in doctors and dentists offices, and at medical facilities including hospitals, clinics and hospices.

"The 40th anniversary of Earth Day is a perfect opportunity to tell Americans the good news about the expanded prescription mail-back program," said Sam Pulcrano, vice president, Sustainability. "It is another way the Postal Service demonstrates its commitment to the environment."

The Postal Service has won more than 75 environmental awards, including 40 White House Closing the Circle, 10 Environmental Protection Agency WasteWise Partner of the Year, Climate Action Champion, Direct Marketing Association Green Echo, and the Postal Technology International Environmental Achievement of the Year, 2009.

For more information about the Postal Service green initiatives, tools and products, visit usps.com/green.

The Postal Service receives no tax dollars for operating expenses, and relies on the sale of postage, products and services to fund its operations.

#

Please Note: For broadcast quality video and audio, photo stills and other media resources, visit the USPS Newsroom at www.usps.com/news.

A self-supporting government enterprise, the U.S. Postal Service is the only delivery service that reaches every address in the nation, 150 million residences, businesses and Post Office Boxes. The Postal Service receives no direct support from taxpayers. With 36,000

retail locations and the most frequently visited website in the federal government, the Postal Service relies on the sale of postage, products and services to pay for operating expenses. Named the Most Trusted Government Agency five consecutive years and the sixth Most Trusted Business in the nation by the Ponemon Institute, the Postal Service has annual revenue of more than \$68 billion and delivers nearly half the world's mail. If it were a private sector company, the U.S. Postal Service would rank 28th in the 2009 Fortune 500.

APPENDIX GROUP 5

Distribution Site Materials

- APPENDIX GROUP 5: Distribution Site Materials
 - APPENDIX 5A: Recruitment letter
 - APPENDIX 5B: Welcome letter
 - APPENDIX 5C: Memorandum of Understanding letter
 - APPENDIX 5D: Memorandum of Understanding
 - APPENDIX 5E: Informational poster
 - APPENDIX 5F: Program question and answer guide
 - APPENDIX 5G: Sample site newsletter

Phase II Area Agency on Aging Recruitment Letter

October 1, 2008

Dear AAA Director,

The Safe Medicine Disposal for ME Program is a program that provides postage-paid envelopes to Maine residents for safe disposal of unused and unwanted medicine. During the past year, the Safe Medicine Disposal for ME Program has been working to establish pilot program sites within a designated four-county area. The program has become such a success within our pilot pharmacy sites that we are now expanding the program statewide. Our first key step is to secure partnering distribution sites across the state that are interested in providing Maine residents with pre-paid envelopes for medicine disposal.

We would like to extend an invitation for your organization to join a growing roster of organizations that are participating as a distribution site for envelopes. As an Area Agency on Aging, you and your staff members represent a critical link to older adults throughout the state. Research indicates that older adults consume far more prescription drugs than any other population, putting them at risk for accumulation of medication that is unneeded and unwanted.

Please consider joining our program as a distribution site. Here is what is required of distribution sites:

- There is no cost to you or to program participants (this is currently a grant-funded program).
- A designated staff person at your location should provide program envelopes to all interested individuals at no cost to them.
- You will be asked to display a sign or flyer at your location alerting the public to the availability of program envelopes.
- You and your staff do not need to answer any questions about the program. We have an established Program Helpline for participants.

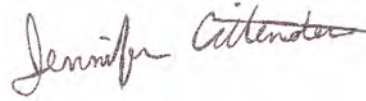
We anticipate that envelopes will be available for distribution within the next few months. Please confirm that your organization is interested in participating in the program. If you are interested in serving as a site, please complete the attached contact information sheet to ensure that we have up to date contact information for you and your site. Return this form to me by e-mail at: jennifer.crittenden@umit.maine.edu or by fax at 207-262-7921. You can expect to receive regular updates on the program as we gear up to go statewide.

Thank you for considering partnering with our program. We hope that you will consider serving as a site for this very important project benefiting Maine residents. Please do not hesitate to contact me with any questions you may have.

Sincerely,

A handwritten signature in black ink that reads "Lenard W. Kaye". The signature is written in a cursive style with a large, stylized 'L'.

Lenard Kaye, DSW/Ph.D.
Principal Investigator

A handwritten signature in black ink that reads "Jennifer Crittenden". The signature is written in a cursive style with a large, stylized 'J'.

Jennifer Crittenden
Program Director

Safe Medicine Disposal for ME Program



March 16, 2010

To: Safe Medicine Disposal for ME Site Contacts

From: Jennifer Crittenden, Program Director

RE: Welcome to the Safe Medicine Disposal for ME Program!

On behalf of the Safe Medicine Disposal for ME Program, we would like to welcome your organization to our growing list of statewide mailback program sites. Our program originally began in the spring of 2008 and was geared toward older adults. It has become such a success that we are now expanding statewide and opening the program to all ages (no longer just for older adults). We expect to be fully operational statewide by the end of November.

Please take a moment to review the items in your welcome folder. These items include a Procedure Guide, Question and Answer Guide, Detailed Fact Sheet, Program Site Listing, Consumer Fact Sheet and a copy of the Memorandum of Understanding (MOU).

Along with the envelopes that have been provided to you, you will find a program sign for display at your site along with consumer education materials related to the program. Feel free to distribute these items as you see fit.

Welcome to the program and please feel free to contact the helpline with any general questions or concerns you may have at 1-866-637-9743.

Thank you for your commitment to health and safety of Maine's citizens.

Sincerely,

A handwritten signature in black ink that reads "Jennifer Crittenden".

Jennifer Crittenden

Program Director

Safe Medicine Disposal for ME Program



March 16, 2010

Dear NAME HERE,

Thank you for agreeing to participate in the next phase of the Safe Medicine Disposal for ME program.

We will arrange for shipment of program envelopes and a welcome packet directly to the address we have on file for your site. We anticipate that these will be delivered to you in November.

Enclosed, you will find a copy of the program MOU. It outlines the basic concepts and expectations of the program. Please sign this form and send it back to the Center on Aging for our files either by mail at UMaine Center on Aging, ATTN: Lynette Roy, Camden Hall, 25 Texas Ave., Bangor, Maine 04401 or by fax at 207-292-7921. Once we have this on file we will be able to arrange for your envelope shipment.

Once again, welcome on board, and please feel free to contact the helpline with questions or concerns at 1-866-637-9743.

Sincerely,

A handwritten signature in black ink that reads "Jennifer Crittenden".

Jennifer Crittenden

Program Director



SAFE MEDICINE DISPOSAL FOR ME PROGRAM

MEMORANDUM OF UNDERSTANDING (WITH PARTICIPATING SITES)

This Memorandum of Understanding (MOU) contains basic provisions which guide the working relationship between both parties. This MOU may be amended, in writing, at any time with the concurrence of both parties and may be renegotiated at the end of Phase II of the program.

PROVISIONS OF THE MEMORANDUM OF UNDERSTANDING

Safe Drug Disposal for ME Program:

- The Program will arrange for drug return envelopes and materials to be mailed to your site or corporate location.
- The Safe Medicine Disposal for ME Program will have a hotline number for site personnel and the public to call in order to ask questions or voice concerns. This is a voice mail system staffed by the University of Maine Center on Aging. Messages will be returned within 2 business days.
- The Program will promote to the public all Phase II participating sites. Marketing materials will include, when possible, the name of the participating pharmacy or site, the physical location of the site, and the site telephone number.
- There is no charge to sites or community members to participate.

Participating Sites:

- All signage must be placed for the public to see, such as on the sales counter, in order to indicate that project envelopes are available. Supplies of program brochures, consumer fact sheets and business cards will be available for sites to distribute.
- Envelopes are not to be provided to group homes, nursing homes, or other facilities for their use. The Safe Medicine Disposal for ME Program is only available to individual citizens at this time.
- Envelopes are to be given free of charge to all who ask. No purchase is necessary.

- Sites are not expected to answer questions regarding the program. Business cards with program hotline contact information will be available for customers seeking further information.
- Sites are expected to use the program hotline if any questions or concerns should arise.
- Sites agree to provide information on a regular basis concerning the number of envelopes available when contacted by program staff.
- Sites agree to proactively provide customers with drug return envelopes in order to promote the program. This program is open to adults of all ages.

By signing and dating this Memorandum of Understanding, I acknowledge that I have read and understand the above stated provisions, and agree to adhere to them as closely as possible. I also agree that I am the primary contact for my site for all future communication with the Safe Medicine Disposal for ME Program.

SITE CONTACT PERSON SIGNATURE: _____ **DATE:** _____

SITE CONTACT PERSON (PRINT NAME): _____

PROGRAM STAFF MEMBER SIGNATURE: _____ **DATE:** _____

PROGRAM STAFF MEMBER (PRINT NAME): _____

Is Your Home Safe?

If you have unused or expired medicine in your home, **you may be at risk** of...

- Theft of medicine by drug abusers
- Poisoning of loved ones and pets
- Taking expired or wrong medicine
- Polluting your environment

Make your home safe by getting rid of unwanted or expired medication through the **Safe Medicine Disposal for ME Program**.



Free postage-paid medicine return envelopes available here for **all Maine residents**.

Ask a staff member for more information.

Safe Medicine Disposal for ME Program



Safe Medicine Disposal for ME Program

What is Safe Medicine Disposal for ME?

Safe Medicine Disposal for ME is a program which provides an opportunity for Maine residents to safely dispose of unused or expired medicine by mail.

What will I be asked to do?

Please ask your customers or clients if they would like an envelope to safely dispose of unused or expired medicine in their home. If they are interested, give them an envelope with a survey and directions inside. Please provide envelopes to anyone who asks for one. No purchase is required and there is no cost to participate.

Who should get the envelopes?

When the program first began, it was specifically designed for older adults. However, the need for safe medicine disposal affects many age groups. In response to this need, the program is now designed for **adults of all ages**. The envelopes are for **individual or family use only**, and are not intended for nursing homes, group homes or other large group returns.

What about participants who want more than one envelope?

Participants may use more than one envelope. Please use your judgment when handing out multiple envelopes. Supplies are limited. Once you run out of envelopes we cannot guarantee that we can provide you with additional envelopes.

How much does it cost?

Nothing. There is no charge to the distribution sites or the participants for the postage-paid envelopes. Funding for this program was provided by the United States Environmental Protection Agency's Aging Initiative.

What do the participants do with the envelopes?

They enclose all unwanted medicine according to the Instruction Booklet included in each envelope and mail the envelope just like any other letter or package. There is a Program Helpline (1-866-637-9743) they can call if they have any questions.

Why are the envelopes numbered?

This is a code number for tracking the envelopes. Participants will call the Program Helpline at 1-866-637-9743 when they mail their envelope and leave only the code number and the date that it was mailed (not their name) on the recording. The code number helps us to know which envelopes to expect and how long they take to get to the Maine Drug Enforcement Agency for storage and disposal.

What if we run out of envelopes?

Please contact the Program Helpline. Envelope supplies are limited and we cannot guarantee that we will have additional envelopes for your pharmacy or organization.

Where does the medicine go?

The envelopes are returned to the Maine Drug Enforcement Agency. The medicine is then cataloged and safely destroyed.

What happens to the surveys?

The confidential surveys are sent to the Maine Drug Enforcement Agency along with the medicine where they are then forwarded on to the University of Maine Center on Aging. The Center will conduct an analysis to determine the types of medicine returned and the reasons for the medicine being returned.

Will I be able to find out the results of this program?

Information about the amount and type of medicine that was returned will be posted on the program website as it becomes available.

What if I have additional questions or concerns about this program?

Please contact the Center on Aging (contact information below) with any questions or concerns you may have.

Updated September 19, 2008

© 2008 University of Maine Center on Aging

Contact Information

If you have questions, please do not hesitate to contact us by e-mail or phone:

E-Mail at: **info@safemeddisposal.com**

Program Helpline at: **1-866-673-9743**

For more information about the program, visit:

www.safemeddisposal.com

Thank you for your participation and for your commitment to well-being of Maine's residents and our environment!

Safe Medicine Disposal for ME Program



SITE NEWSLETTER (March 10, 2009)

This newsletter is specifically designed for pharmacies, healthcare offices, police departments and community agencies that are distributing envelopes through the Safe Medicine Disposal for ME Program (mailback program)

Program Updates

Since the mailback program began we have collected over **700lbs of medicine**, from over **1600 envelopes**. About 10% of the returned medicine is controlled (narcotics).

The program went statewide and opened to **individuals of all ages (no longer just older adults)** in November 2008. We have over 100 distribution sites that include pharmacies, several police departments and agencies. We also have several more potential sites on a waiting list.

The Helpline remains active receiving messages from people who have mailed in envelopes, have questions about the program, and those who want to become a distribution site.

Need more supplies?

If you need more envelopes, signs, pamphlets, tip sheets or business cards please leave a message on the Helpline, the number is 1-866-637-9743.

We are currently out of envelopes but are planning to get more in the coming months. In the meantime we are putting

sites on a resupply list to receive envelopes as soon as we get them.

Community Volunteers

We have several community volunteers trained on the Safe Medicine Disposal for ME Program. Volunteers are located in Aroostook, Hancock, Kennebec, Knox, Oxford, Penobscot, Piscataquis, and York counties. If you would like a volunteer to work with you on a disposal or education/outreach event please contact us and we can connect you with a volunteer in your area.

How to Contact us:

Helpline: 1-866-637-9743

Website:

www.safemeddisposal.com

E-mail:

info@safemeddisposal.com

What happens to the medicine that is returned?

All envelopes that are returned are inventoried by pharmacists and pharmacy techs. Medicine is then sorted for disposal (incineration). See page 2 for pictures.

**Continuing Education Opportunity:
Save the Date!**

2009 International Symposium on
Pharmaceuticals in the Home and
Environment

October 18-20, 2009

Point Lookout Resort and Conference Center,
Northport, Maine

Continuing Education Units (CEUs) will be
offered!

For more information visit:

www.mainebenzo.org/2009conference.htm

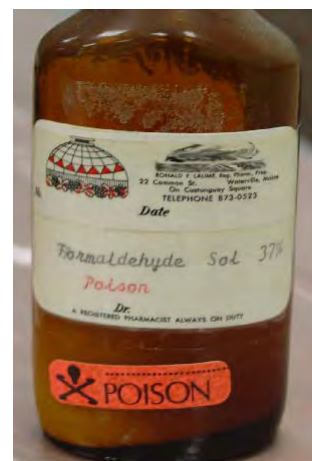


**Unfortunately we receive many
bottles of unopened medicine
representing thousands of
wasted healthcare dollars.**

**Here are some interesting pictures
from our inventory sessions:**



Cataloging in action



**It is not uncommon to see older
medicines like this bottle of
Formaldehyde**



**This is just a small sample of
what we have received**



**Medicine that is mixed
together without a bottle as
shown here creates challenges
for sorting and identification.**

APPENDIX 6
Helpline & Volunteer Information
Staff and Volunteer Question & Answer Guide

Safe Medicine Disposal for ME: Staff and Volunteer Question and Answer Guide

What is Safe Medicine Disposal for ME?

Safe Medicine Disposal for ME is a program which provides an opportunity for individuals and families in Maine to safely dispose of unused or expired medicine by mail.

What are the benefits of using this program?

- Reduce the chances for medication errors.
- Keep medicine away from children and pets.
- Keep medicine away from people who might misuse it or steal it.
- Dispose of medicine in a way that protects Maine's environment.

How can I get more information?

For technical questions, please contact the University of Maine Center on Aging Program Helpline at:
1-866-637-9743

Or send an e-mail to:
info@safemeddisposal.com

For general information about the program, log on to:
www.safemeddisposal.com



Funding for this program was provided by the EPA Aging Initiative.

Can I participate in this program?

The program is open to all individuals and families who have unused and unwanted medicine in need of disposal. The envelopes are for individual or family use only, and are not intended for nursing homes, group homes, medical facilities, or other large group returns.

How much does it cost?

Nothing. There is no charge to the pharmacies distributing the envelopes or the participants returning medicine in the postage-paid envelopes. Funding for this program was provided by the United States Environmental Protection Agency's Aging Initiative.

Where can I get an envelope?

A listing of participating locations throughout Maine is available online at www.safemeddisposal.com or you can e-mail info@safemeddisposal.com or call our helpline for assistance at 1-866-637-9743.

Can you send me an envelope?

We are able to, on a limited basis, mail envelopes directly to individuals who are unable to get to a participating pharmacy to obtain an envelope.

Can I use more than one envelope?

Yes, if all your medicine does not fit in one envelope you can use more than one envelope. Please fill out a survey for each envelope that you mail.

Can I use my own envelope or box?

No. Please only use the special envelopes provided by the program. They have been approved by the US Postal Service for this purpose. If all of your medicine cannot fit into one envelope, you may request additional envelopes from your nearest participating pharmacy or via the program helpline.

What should I do with the envelope?

Enclose your unwanted or expired medicine according to the directions in the booklet found in each envelope, then mail the envelope just like any other letter or package. You can mail both liquids and pills in the same envelope as long as you follow the instructions in the booklet provided. If you can't find your instruction booklet, you can view a copy on the program website or we can send you one by mail.

What medicine can I dispose of through this program?

This program accepts most kinds of prescription and over the counter medicine. Please do not include more than a total of 4 ounces (or 120mL) of liquids, creams, and/or gels.

Is there any medicine that I can't dispose of through this program?

Yes, some specialized medicine requires the use of a manufacturer disposal program. Check the packaging or contact your pharmacist for more information. Absolutely no syringes, medical devices (such as blood sugar monitors, etc.), needles, epi-pens broken glass, or sharp objects of any kind can be included. Even if they are wrapped or packaged, they may not be included. Contact your doctor or pharmacist for disposal options for these items.

Can I return medicine if it not in its original bottle?

Yes. Returning medicine in its original bottle will make it easier for pharmacist to identify it. However, if you cannot return it in its original bottle, you can put in in a small container or zip lock bag before placing it in the envelope. Please write down the name of the medicine, the dose, and the number of pills originally prescribed, if you know it.

Can I dispose of pet or veterinary medicine?

Yes, if there is room in your envelope after enclosing any prescription medicine you want to dispose of, you may include pet or veterinary medicine. However, we recommend that you contact your local veterinary clinic, animal shelter, humane society, or animal rescue group to see if they are able to use this medicine.

Can I dispose of over the counter medicine, herbal supplements, or vitamins?

Yes, if there is room in your envelope after enclosing any prescription medicine you want to dispose of, you may include over the counter medicine, herbal supplements, or vitamins.

Can I dispose of medicated patches?

Yes. If the patches are not already in a wrapper, place them in a zip lock bag before placing them in the envelope.

Can I dispose of inhalers?

Yes, if there is room in your envelope after enclosing any other prescription medicine you want to dispose of, you may include inhalers.

Will you be collecting information about me when I return my medicine?

Program staff will not be collecting any personal information about you from the medicine bottles that is returned. If you wish, you may mark out personal information from the labels on your medicine bottles. Please do not mark over the name of the medicine or number of pills. We will be collecting information only about the medicine that is returned in general to better understand the amount and kind of medicine that is piling up in Maine medicine cabinets. Information that you provide on the survey will help us to understand this issue. The survey is confidential and you can skip any questions you do not wish to answer.

Why are the envelopes numbered?

This is a code number for tracking the envelopes. Please call the Program Helpline at 1-866-637-9743 when you mail your envelope and leave only the code number and the date that it was mailed (not your name) on the recording. The program is confidential, and any information about the returned medicine will not be linked to personal information. The code number helps us to know which envelopes to expect and how long they take to get to the Maine Drug Enforcement Agency for storage and disposal.

What if I mailed my envelope but forgot to write down the code number first?

Call the Program Helpline at 1-866-637-9743 and provide the date that you mailed the envelope and simply state that you do not know what the code number is.

Where does the medicine go?

The envelopes are returned to the Maine Drug Enforcement Agency. The medicine is then cataloged and safely destroyed.

Do I need to fill out the survey in order to send in medicine?

You do not need to fill out the survey in order to participate in the program. The survey is optional. We encourage you to consider providing a response to the survey because this research will help us to improve the program and to understand why medicine goes unused in Maine.

What happens to the surveys?

The confidential surveys are sent to the Maine Drug Enforcement Agency along with the medicine where they are then forwarded on to the University of Maine Center on Aging. The Center will conduct an analysis to determine the types of medicine returned and the reasons for the medicine being returned.

Will I be able to find out the results of this program?

Information about the amount and type of medicine that was returned is available at <http://www.safemeddisposal.com/Research.php>. You can also request this information by e-mail at: info@safemeddisposal.com or by calling 1-866-637-9743.

I am a pharmacist. How can my pharmacy participate in the program?

Please call the helpline at 1-866-637-9743 and leave a message indicating you would like to become a site. A staff member will return your call and provide you with the paperwork necessary to become a site. As of April 2009 we are maintaining a waiting list for interested sites but we anticipate new sites will be welcomed to the program in the summer of 2009.

Updated April 23, 2009

© 2008 University of Maine Center on Aging

APPENDIX GROUP 7

Mailback Envelope Materials

- APPENDIX Group 7: Participant Mailback Envelope Materials
 - APPENDIX 7A: Instruction booklet for preparing and returning medicine
 - APPENDIX 7B: Informed consent for consumer survey
 - APPENDIX 7C: Consumer survey

Safe Medicine Disposal for ME Program



A program for all Maine
residents!


INSTRUCTION BOOKLET

Information on how to
prepare and return your
medicine for proper disposal

Helpline: 1-866-637-9743




Turn to view



| Steps | <div>Safe Medicine Disposal for ME Program</div> <div>5 Step Quick Instruction Guide</div> |
|-------|---|
| 1 | <div>Read through <u>this booklet</u> for information on the Safe Medicine Disposal for ME Program.</div> <div>**Keep this booklet. Do not mail it with your medicine.**</div> <div>If you have questions, please call our Helpline: 1-866-637-9743</div> |
| 2 | <div>Place your unused medicine into the <u>postage-paid envelope</u>.</div> <div></div> <div><div>✓ No sharp objects or needles</div><div>✓ No batteries, electronics, or medical devices (hearing aids, blood sugar monitors)</div><div>✓ No thermometers</div><div>✓ Leave all medicine in the bottle/packaging</div><div>✓ Containers with liquids, gels, or creams are to be wrapped in a paper towel and sealed in a zip lock bag before you put them in the envelope. Only 4 ounces (or 120 ml) total of liquids, gels or creams can be mailed.</div></div> |

Turn to view



| | |
|---|--|
| 3 |  <p>Complete the <u>enclosed survey</u> and place it in the envelope with your medicine. DO NOT WRITE YOUR NAME ON THE SURVEY OR PROGRAM ENVELOPE</p> |
| 4 |  <p>Make a note of your <u>envelope code number</u>. It is a four digit number located in the bottom left hand corner of your envelope. Write it here: ____ _</p> |
| 5 | <p><u>Seal envelope and mail it</u>. No postage is needed. Mail the postage-paid envelope as you would any other letter or package through the U.S. Mail.</p> |
| | <div><p>Thank you for participating! For more information: Call: 1-866-637-9743 Visit: www.safemeddisposal.com</p></div> |

The Safe Medicine Disposal for ME Program

Safe Medicine Disposal for ME is administered by the University of Maine Center on Aging and Safe Medicine for Maine in partnership with the Maine Drug Enforcement Agency, the Maine Department of Environmental Protection, the United States Postal Service, and many other organizations concerned about protecting the health and welfare of Maine's citizens. Because our program partners are committed to your health and safety, you are invited to take part in this exciting new program. The program was created to give Maine residents a safe disposal option for unused and unwanted medicine.

By mailing back your unused medicines, you:

- ⇒ Reduce your risk of taking medicine in error that may be harmful or cause interactions with other medicine
- ⇒ Reduce wasted healthcare dollars by contributing to important research
- ⇒ Dispose of your medicine in a way that protects Maine's environment and prevents groundwater contamination
- ⇒ Get unwanted medicine out of your home and away from people who may want to steal your medicine or take it illegally

Where will my medicine go?

All medicine that you place in the pre-paid envelope provided will be sent to the Maine Drug Enforcement Agency for proper disposal.

How much does this cost?

There is **no cost to you** to participate. Postage and disposal costs have been paid through support from the Maine Drug Enforcement Agency and other in-kind donations from program partners.

Instructions

Before you begin:

Gather the unused and/or expired medicine you wish to mail for disposal. Leave all medicine in its original container(s).

If you wish, you may use a marker to black out



your name
and personal
information on

the medicine bottle.

However, please **do not**
black out the

name and quantity of the medicine. This helps us to identify the medicine for disposal.

Please leave medicine in the original container(s). Do not black out the name of the medicine or the number of pills.

The Food and Drug Administration (FDA) requires special handling of certain drugs to ensure safe distribution and use. Due to these requirements, some manufacturers provide for their own disposal programs. Please check the medicine package or contact your pharmacist for more information about manufacturer disposal programs that may exist for the medicine you have.

Please place all medicine you wish to dispose of into the postage-paid envelope provided.

Do not put the following items into the envelope:

1. **DO NOT** place loose pills into the envelope. Leave all pills in their original bottles. This will help us to identify the drug for disposal. If you need more than one envelope, please request an additional envelope from a participating site or call 1-866-637-9743.



2. DO NOT put syringes or sharp objects into the envelope. No syringes, sharps, or needles or other items that may cause injury to the postal carrier or program staff are to be placed into the postage-paid envelope.



Even if these items are packaged or wrapped, they are not to be placed in the envelope. If you would like more information about proper disposal of sharps, please contact your healthcare provider or visit: www.safeneedledisposal.org

3. No batteries, electronics, medical devices (hearing aids, blood sugar monitors), or thermometers should be placed into the envelope.

No needles, loose pills, pills in baggies, broken glass, sharp objects, medical devices, or thermometers are to go into the envelope.

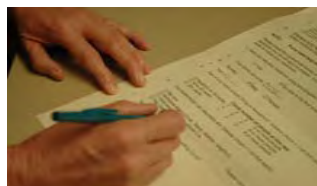


Only a total of 4 oz (or 120ml) of liquids, gels, and creams total can be mailed back. Wrap them in paper towels, place them in a zip lock bag, and put it in the envelope. Be sure to seal the zip lock bag and envelope tightly.

Liquids, Gels, and Creams

The total combined volume of all liquids, gels, and creams returned should be 4 ounces (about 120 ml) or less. Please wrap each container of liquid, gel, or cream in a paper towel and place it in a zip-lock bag before placing them in the envelope with any other medicine.

Once all your medicine is placed in the postage-paid envelope, complete the survey provided. Place your completed survey in the envelope and seal it. It is now ready to be mailed.





Complete the survey and place it in the envelope with your medicine.

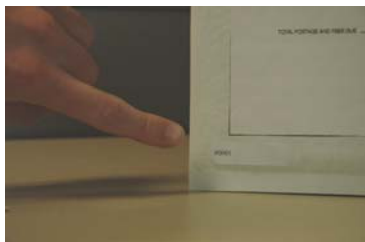


If you have questions about what to put into the envelope, please call the

Program Helpline at: 1-866-ME-RX-RID (1-866-637-9743).

Visit our website: www.SafeMedDisposal.com

E-Mail: info@SafeMedDisposal.com



Find the 5-digit code number in the bottom left hand corner of your envelope.



Write it here and

keep for your records: _ _ _ _ _

Mailing Your Envelope

Mail the envelope as you would any other letter or package through the U.S. Mail.

There are several choices available to you including:

- Hand the envelope directly to your mail carrier,
- Bring it directly to your local Post Office for mailing,
- Place the envelope into a **blue** United States Postal Service mailbox at your local Post Office or other locations in your area, or
- Place the envelope in your home mailbox.



Thank you for participating in this program! If you have any further questions or comments about the program please call:

1-866-637-9743

Please keep this booklet for your records.

Program Partners

The program has been made possible by the following organizational partners:



With us, it's personal.



Community Medical
Foundation for Patient Safety
The Community of Competence™ and Foundation for Life



Please see back page for full listing of program partners

Partners for this program include the:

- ◆ University of Maine Center on Aging
- ◆ U.S. Environmental Protection Agency
- ◆ U.S. Postal Service
- ◆ Community Medical Foundation for Patient Safety
- ◆ Safe Medicine for Maine
- ◆ Maine Department of Environmental Protection
- ◆ Maine Drug Enforcement Agency
- ◆ U.S. Drug Enforcement Administration
- ◆ Rite Aid Pharmacies
- ◆ CVS Pharmacies
- ◆ Maine Office of Elder Services
- ◆ Maine Office of Substance Abuse
- ◆ Maine Association of Psychiatric Physicians
- ◆ Maine Office of the Attorney General
- ◆ Maine Pharmacy Association
- ◆ Maine RSVP Programs
- ◆ Margaret Chase Smith Policy Center
- ◆ Maine Medical Association
- ◆ Maine Office of Adult Mental Health
- ◆ Miller Drug
- ◆ National Council on Patient Information and Education
- ◆ Northern New England Poison Center
- ◆ Villanova University Center for the Environment
- ◆ Maine Department of Health and Human Services
- ◆ Maine Council for Child and Adolescent Psychiatry
- ◆ Community organizations and pharmacies throughout Maine

Edition: September 2, 2009

© 2009 University of Maine Center on Aging

Instructional photographs: © 2007 Liv Kristin Robinson

Funded through a Fund for Healthy Maine allocation to the Maine Drug
Enforcement Agency

Please Read
Survey Instructions and Informed Consent
Safe Medicine Disposal for ME Program

As a Maine resident, you are being given the opportunity to safely and properly dispose of your unused medicine at no cost. As a participant taking advantage of this service, you are offered the opportunity to tell us more about the medicine you are returning and the reason for disposal. The University of Maine Center on Aging and Safe Medicine for Maine has received funds from the Maine Drug Enforcement Agency to offer this medicine return program. We will be studying the types of unused medicines Maine residents are interested in disposing.

As a medicine return program participant, you are invited to take part in this important research currently being done throughout Maine. Information collected from the survey provided will also tell us more about the reasons for disposal and the types of medicines that are piling up in homes across the state. Research findings will help us to design more medicine disposal opportunities for Maine residents and for use nationally.

If you would like to contribute to this research, please take a moment to complete the enclosed survey.

What will you be asked to do?

If you decide to participate in the research, you will be asked to complete the enclosed survey. It will take approximately 10-15 minutes to complete this survey. Please return the survey in the pre-paid envelope provided along with the medicines you are returning. You may skip any questions you do not want to answer.

Risks of participating in the survey

Except for your time and inconvenience, participation presents no more risk than you would normally experience throughout the course of your day.

Benefits of participating in the survey

There is no immediate benefit to you for taking the survey.

Confidentiality

This survey is anonymous. The information you provide on your survey will be kept private. Only the Center on Aging staff and staff from the Maine Drug Enforcement Agency (MDEA) will have access to your returned survey. **Please do not write your name on your survey.** Surveys will be collected from the returned envelopes once they are opened for inventory at the MDEA. After the envelopes are opened, all surveys will be kept at the Center on Aging for secure storage and reporting.

We will not collect personal information from returned medicine bottles (name, physician, etc.). If you wish to black out your name and personal information on the medicine bottle, be sure to leave the medicine name and quantity visible. This will help us identify the medicine for research and disposal. Information you provide on the survey will be linked to information on the type and amount of medicine you returned. At the conclusion of the study, medicine and containers will be destroyed. All returned medicine will be destroyed in an environmentally friendly way by the Maine Drug Enforcement Agency.

Any quotes or information used in reports and papers about this research will not be linked to your personal information. The survey you provide us will be kept indefinitely by the Center on Aging.

Voluntary

Your participation in this research is voluntary. You may choose to participate or not participate. You may skip any questions you do not wish to answer. You do not need to fill out a survey in order to return medicine.

Along with this information sheet you will find the survey that we are asking you to complete. Completing the survey and returning it in the envelope provided along with the medicine you are returning will let us know that you want to be a part of this research.

Contact Information

If you have questions about the program or how to use the envelope, please call 1-866-637-9743.

If you have questions about the survey and research you may reach the Project's Principal Investigator, Dr. Lenard Kaye, at 207-262-7922 or len.kaye@umit.maine.edu. If you have any questions about your rights as a research participant, please contact Gayle Anderson, Assistant to the University of Maine's Protection of Human Subjects Review Board, at 207-581-1498 or e-mail gayle.anderson@umit.maine.edu.

Thank you!

DO NOT write your name (or the name of the person for whom you are returning medicine) anywhere on this form.

Safe Medicine Disposal for ME Program Survey



INSTRUCTIONS:

1. Before completing this survey, please read through the survey instructions provided to you with your envelope.
2. This form is for research purposes only. Research findings will help us to design more medicine disposal opportunities for Maine residents and create a national model.
3. You do not need to complete this survey in order to return your medicines. If you choose to take the survey, please return it in the same pre-paid envelope given to you to return your medicine.

NOTE: If you need help filling out this form, please call: 1-866-637-9743

Please check the appropriate boxes or write in the spaces provided. You may skip any questions you do not want to answer.

**1. Have you returned medicine using *this* mailback program before?
(Please check (✓) one)**

- ☐ Yes ☐ No, this is my first time returning medicine using *this* program.

Your age: _____years

2. The medicine(s) I am disposing is: (Please check (✓) all that apply)

- ☐ My own medicine
☐ A relative's medicine
☐ A deceased friend or relative's medicine
☐ A friend's medicine
☐ Pet/Veterinary medicine
☐ I don't know whose medicine it is

For the questions below, please tell us about yourself and the medicine you are returning. If you are returning medicine for someone else or for more than one person, **please tell us about the person for whom most of the medicine was prescribed.**

3. Home zip code: _____

4. Gender: ☐ Male ☐ Female

5. Age: _____years

6. Are there any people living in the household in the following age groups? (Please check (✓) all that apply)

- ☐ Newborn to 10 years
☐ 11 to 20 years
☐ 21-64 years
☐ 65+ years

DO NOT write your name (or the name of the person for whom you are returning medicine) anywhere on this form.

7. How did you normally dispose of your unused and unwanted medicine before today? (Please check the method you used most often)

- ☐ Flush down the toilet
- ☐ Put in trash
- ☐ Bring to a drug collection event or give to law enforcement officer
- ☐ Don't know
- ☐ Other: _____

8. Where did you get these medicines? (Please check (✓) all that apply)

- ☐ Sample given to me at the doctor's office
- ☐ Local pharmacy
- ☐ Internet pharmacy
- ☐ Mail order pharmacy
- ☐ Given to me by a friend or family member
- ☐ Other (please list): _____

9. Why do you want to get rid of these medicines? (Please check (✓) all that apply)

- ☐ Doctor told me to stop taking the medicine(s)
- ☐ Doctor gave me new medicine(s) to take instead
- ☐ I had a reaction or allergy to the medicine(s)
- ☐ I did not like the side effects
- ☐ I did not want to take it
- ☐ I got better/did not need it any more
- ☐ I don't want anyone else to use them
- ☐ Other (please list): _____
- ☐ I don't know/I don't remember

10. What is the most important reason behind your decision to use this program?

Please place only one check by the most important reason to you.

- a) Best for the environment _____
- b) Safest for me and my family _____
- c) Other: _____

11. How important are the following features of this program?
Please rank from 1-3 with 1 being the most important and 3 being the least important.

- a) Convenient to use _____
- b) Free to use _____
- c) Anonymous _____
- d) Other: _____

12. How useful is this medicine mail-back disposal program to you? (please circle)

Very useful Useful Somewhat useful Not useful

13. What can we do to improve this program? (please write in)

+++++
When complete, please fold the survey and place it into the envelope along with the medicines you are mailing back. For more information about the Safe Medicine Disposal for ME Program please visit: www.safemeddisposal.com, e-mail: info@safemeddisposal.com or call 1-866-ME-RX-RID (1-866-637-9743). **Thank you.**

APPENDIX GROUP 8

Consumer and Community Education Items

- APPENDIX GROUP 8: Consumer and Community Education Presentation Materials
 - APPENDIX 8A: Sign-in sheet for community presentations
 - APPENDIX 8B: PowerPoint presentation
 - APPENDIX 8C: Program information handout
 - APPENDIX 8D: Community presentation evaluation form
 - APPENDIX 8E: Guidelines for community volunteers
 - APPENDIX 8F: Self-report timesheet for community volunteers

Sign in Sheet

Safe Medicine Disposal for ME
Community Education Presentation

Thursday, October 16, 2008

Rockland

| | Print Name | County of Residence | Age |
|----|------------|---------------------|-----|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 10 | | | |
| 11 | | | |
| 12 | | | |
| 13 | | | |
| 14 | | | |
| 15 | | | |
| 16 | | | |
| 17 | | | |
| 18 | | | |
| 19 | | | |
| 20 | | | |

SAFE MEDICINE DISPOSAL FOR ME

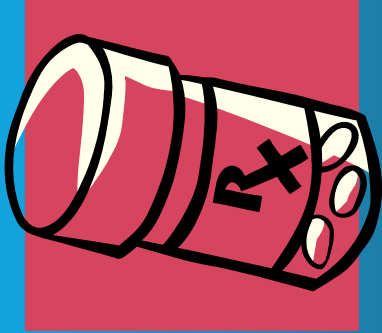


A way for Maine's citizens to safely and properly get rid of unused or expired medicine

Funded by the U.S. EPA (Grant #CH-83336001-0)



Introduction



Safe Medicine Disposal for ME
is a way for Maine's citizens to
safely and properly get rid of
unused or expired medicine

Overview of Program

- ❖ Postage-paid envelopes are taken home to mail back unused and expired medicine
- ❖ An Instruction Booklet, Survey, and Survey Instructions are included in each envelope
- ❖ If participants need help, they can call the Program Helpline at

1-866-637-9743

Program Model



- Program Participants



- Secure delivery to Maine Drug Enforcement Agency



- Envelopes received, logged, catalogued and destroyed under MDEA custody

Program Goals

- Remove unneeded prescription drugs from circulation
- Disposal in compliance with applicable state and federal laws and sound environmental practices



Test your knowledge about Safe Medicine Disposal



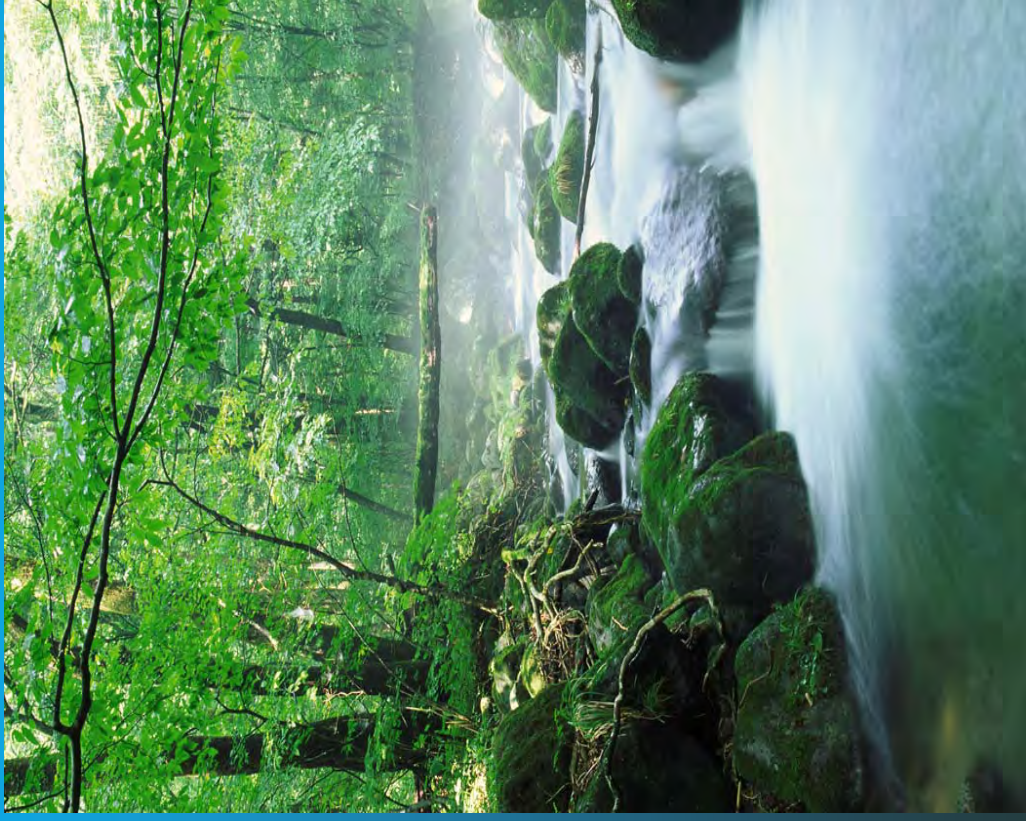
Please take this
time to complete
the first page of the
evaluation form.

Focus Areas

- The Environmental Impact of Pharmaceuticals
- Teen Prescription Drug Abuse in Maine
- Medication Safety

Environmental Impact of Pharmaceuticals

In a recent study by the Maine Dept of Environmental Protection (DEP), Pharmaceuticals and Personal Care Products (PPCPs) were found in 18 out of 19 samples with a majority of sites having 3 or more types of PPCP present.



Environmental Impact of Pharmaceuticals

Facts from across the U.S.:

- Pharmaceutical drugs are present both from human waste and from intentional flushing of prescription drugs in the toilet.
- In every metropolitan area where the public drinking water has been tested, trace amounts of pharmaceuticals have been found.

Environmental Impact of Pharmaceuticals

Impact on us:

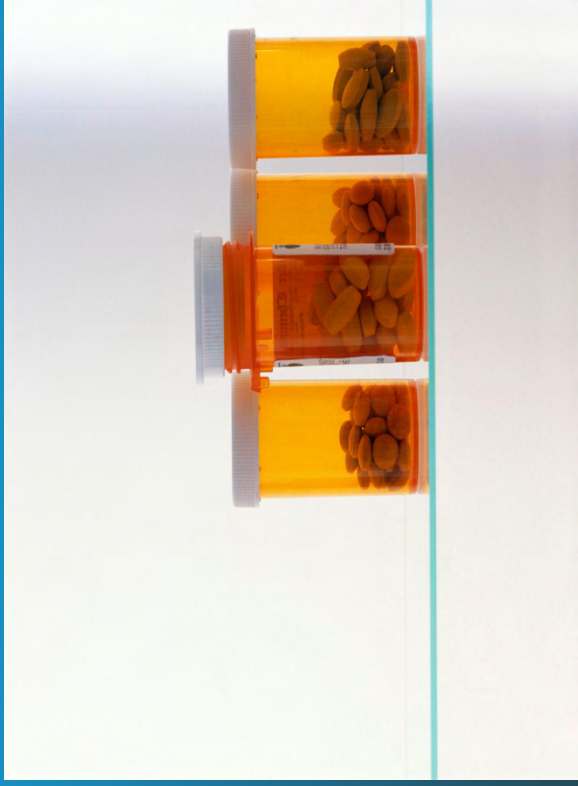
- The federal government currently does not have regulations or standards in place to control pharmaceuticals found in drinking water.
- Waste water treatment facilities are not equipped at this time to deal with screening for these drugs or removing them from the water
- These drugs are finding their way into drinking water and are being ingested by humans wildlife, and fish



Environmental Impact of Pharmaceuticals

What Can You Do?

- Utilize local prescription mail-back or collection programs to dispose of your unused/unwanted medications.
- Do not keep medications stockpiled in your home and keep careful track of your prescriptions.
- Participate in the Safe Medication Disposal for ME program by calling 1-866-637-9743.



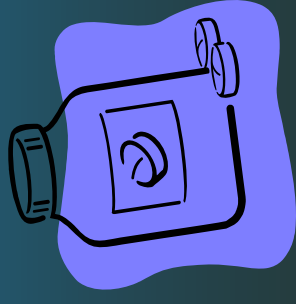
Teen Prescription Drug Abuse in Maine

- According to results taken from the 2006 Maine Youth Drug and Alcohol Use Survey, an average of 12% of teenagers from grade six through 12 across the state reported experimenting with prescription drugs.
- Youth prescription drug abuse is a problem in Maine. About 1 in 5 Maine youth grades 9-12 report having used a prescription drug not prescribed to them to get high. Non-medical use of prescription drugs is the second most popular category of drug abuse after marijuana.



Facts About Teens and RX Abuse

- Nearly one in five teens report abusing prescription medications to get high.
- Teens are misusing everything from pain relievers to stimulants, sedatives and tranquilizers.
- Many teens believe that prescription drugs are safer than alcohol or illicit drugs, and that abusing them isn't risky.



“Pharm” Parties

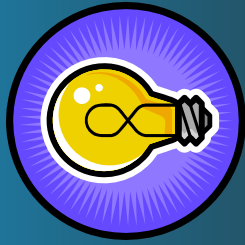
- One of the fastest growing trends with teenage prescription drug abuse is the Pharm Party. These are parties where each person brings bottles of prescription medications that they can find to a party where the medications are then put into a punch bowl for everybody to take like candy. Other names for this are “skittling” and “fish bowling”.



Myths & Facts



Myth – Prescription painkillers, even if they are not prescribed by a doctor, are not addictive.

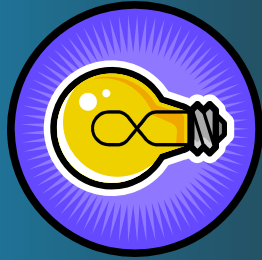


Fact – Abusing certain prescription painkillers is similar to abusing heroin.

Myths & Facts



Myth – There is nothing wrong with using prescription drugs without a doctor’s consent.

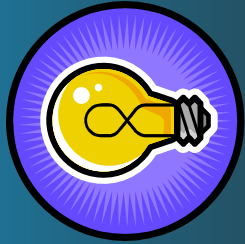


Fact – Taking prescription medicine that your doctor didn’t prescribe and doesn’t know about can result in a dangerous situation if he or she actually prescribes medicine for you that should not be mixed with what you are abusing “on the sly”.

Myths & Facts

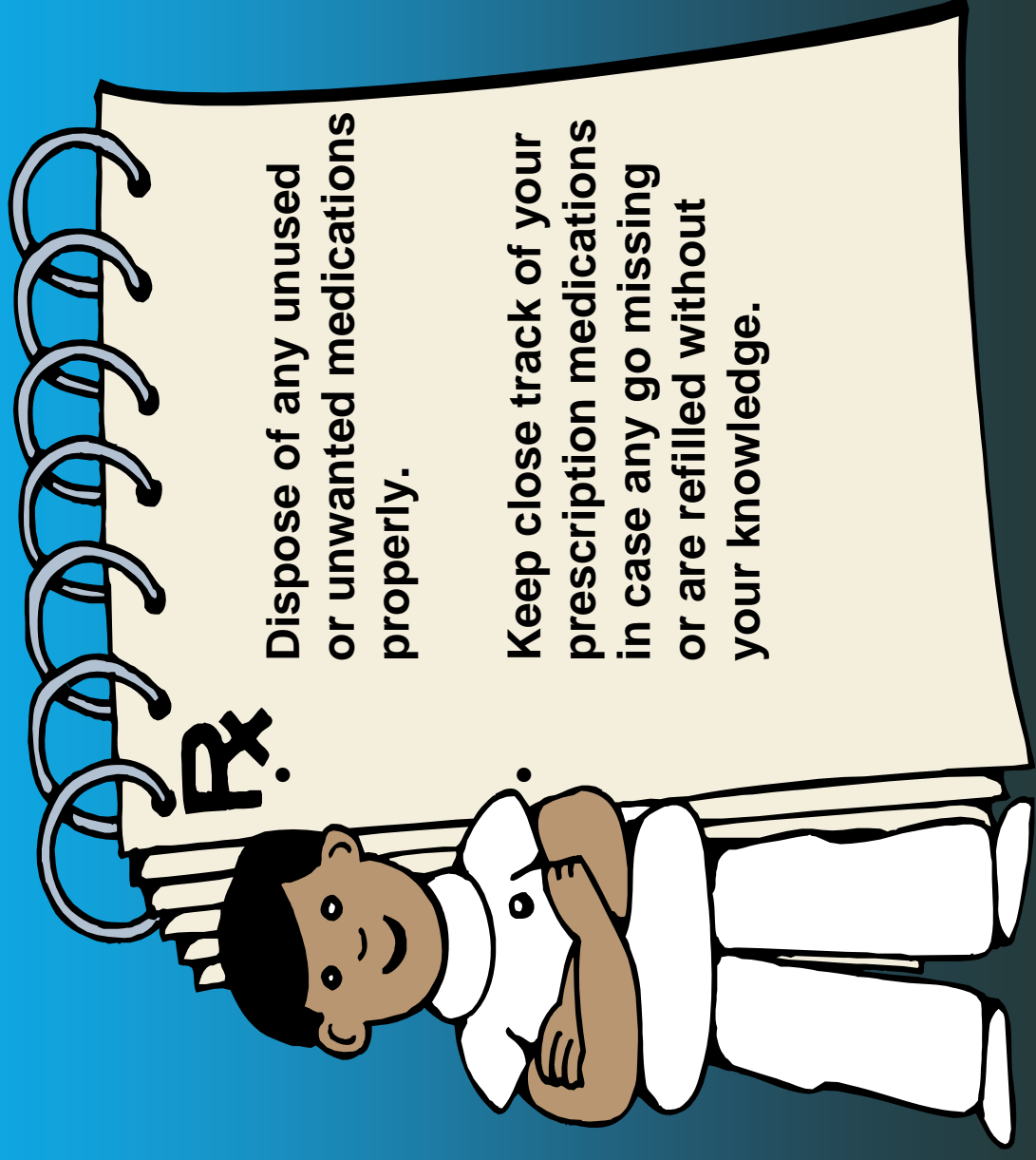


Myths – If a prescription drug is legal and widely available, it must be safe.



Fact – Prescription drugs are safe when used correctly under a doctor's supervision. But taking prescription drugs that aren't intended for you and/or mixing them with alcohol or illicit drugs can result in potentially deadly consequences.

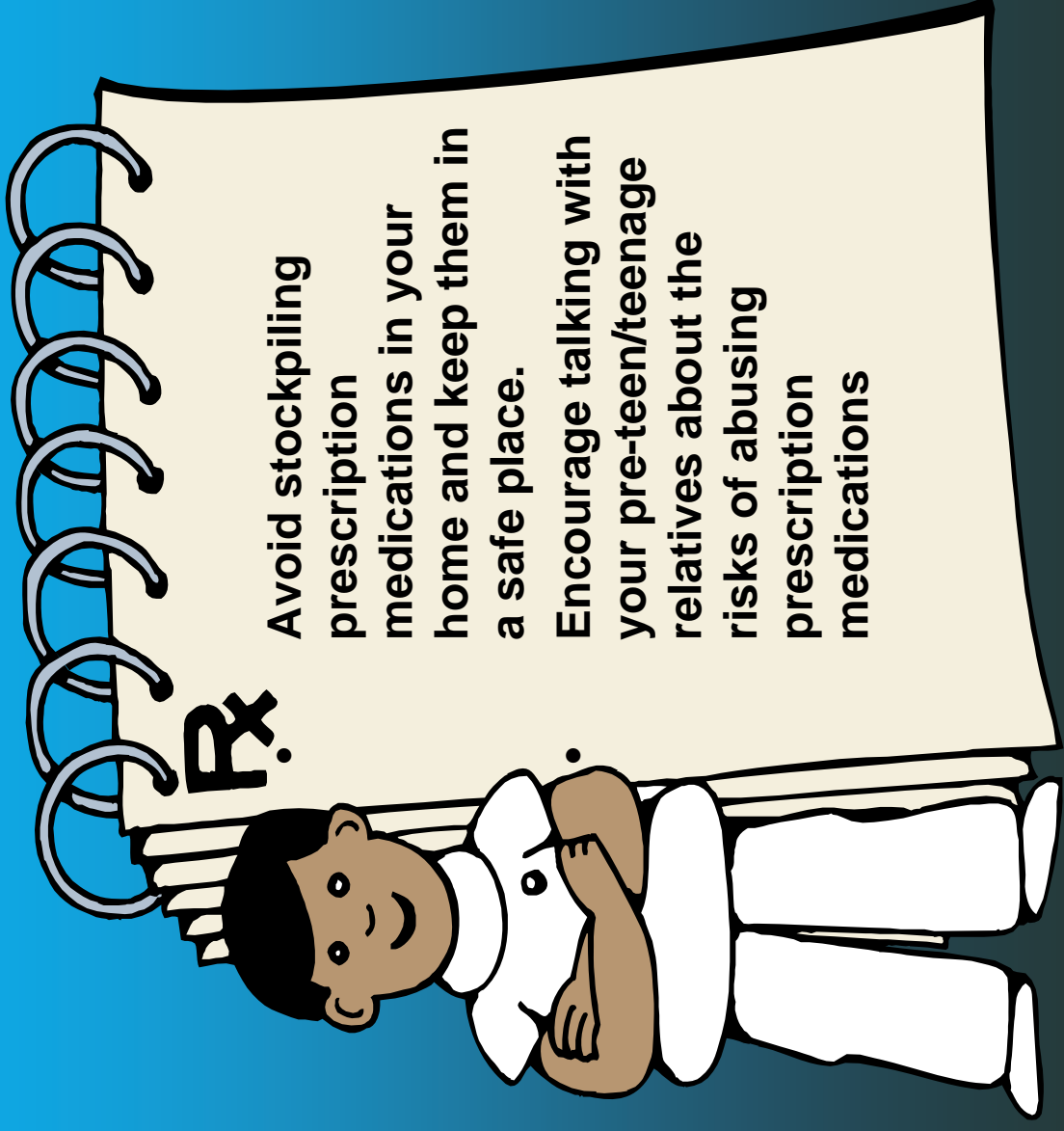
Ways You Can Help:



Dispose of any unused or unwanted medications properly.

Keep close track of your prescription medications in case any go missing or are refilled without your knowledge.

Ways You Can Help



**Avoid stockpiling
prescription
medications in your
home and keep them in
a safe place.**

**Encourage talking with
your pre-teen/teenage
relatives about the
risks of abusing
prescription
medications**

Medication Safety

Reasons why keeping unused or expired drugs in your home is not safe:

- Over 40% of poisoning reported to the poison control center are from mishandling or misuse of prescription drugs.
- Those who abuse prescription drugs often meet their own needs by stealing drugs or stealing property in order to buy drugs.

Medication Safety

Disadvantages of some methods of disposal:

- If medications are burned, they can release pollutants into the air
- If they are thrown out, they can be scavenged and sold illegally
- If medications are flushed, they can have damaging effects on the environment



Remember to:

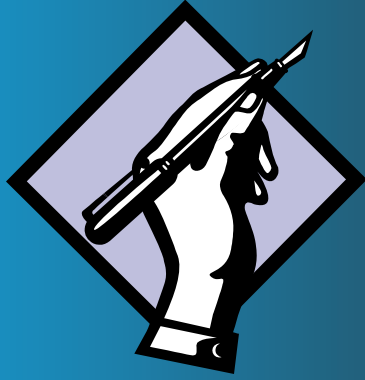
- Review the contents of your medicine cabinet regularly
- Check expiration dates on your prescription and non-prescription medication
- Store medicine safely, out of the reach of children and in a locked cabinet if possible



How Can you Safely Dispose of Medications

- Utilize the Safe Medicine Disposal for ME Program
- Contact your local law enforcement office to see if they sponsor a medication take-back event or drug drop off day
- Contact Maine Poison Control Center at **1-800-222-1222**

Evaluation & Questions



Please feel free to ask questions
at this time, and kindly
complete page two of the
evaluation form.

Thank you!

Source Citations

- Donn, J., Mendoza, M. and Pritchard, J. (2008, March 10). *Drugs found in drinking water*. USA Today. Retrieved from http://www.usatoday.com/news/nation/2008-03-10-drugs-tap-water_N.htm
- Maine Office of Substance Abuse. (2004). The cost of alcohol and drug abuse in Maine 2000 executive summary. Retrieved from www.maine.gov/dhhs/osa/pubs/data/2004/costsummary04.pdf
- Maine Safe and Drug-Free Schools and Communities Act Program. (2006-2007). Report on incident of prohibited behavior and drug and violence prevention. Retrieved from www.mainesdfsa.org/pdf/lobster0607.pdf
- Project AWARE. (unknown). Parents: Are you aware? Retrieved from www.projectaware.net/pdf/pa_parents.pdf retrieved August 8, 2008.
- National Institute on Drug Abuse. (2008). *Prescription Medications*. Retrieved August 8, 2008, from <http://www.drugabuse.gov/drugpages/prescription.html>

Safe Medicine for ME

- Please feel free to call the project hotline for additional information or with any questions at:

1-866-637-9743

Or you can email:

info@safemeddisposal.com

Mailing Instructions

At participating pharmacies, participants will find a postage-paid envelope for disposal of unwanted medicine



The envelope will contain:

- An Instruction Booklet explaining how to prepare and mail unwanted medicine
- A Survey to be filled out and returned with the medicine
- Survey Instructions and an Informed Consent for completing the Survey

Envelopes are for individual safe medicine return only!

- The program envelopes are for individual or family use only
- Program envelopes are not appropriate for institutions, group homes, or assisted living facilities to use for disposal of group medicine collections



MAINE DEA
PO BOX 1480
WESTBROOK ME 04098

FIRST CLASS

POSTAGE DUE COMPUTED BY DELIVERY UNIT

TOTAL POSTAGE AND FEES DUE \$ _____
POSTAGE \$ _____

MERCHANDISE RETURN LABEL
WESTBROOK ME 04092
PO BOX 1480
MAINE DEA

POSTAGE WILL BE PAID BY ADDRESSEE

POSTAGE DUE UNIT
U S POSTAL SERVICE
775 MAIN ST
WESTBROOK ME 04092



NO POSTAGE
NECESSARY
IF MAILED IN
THE UNITED
STATES

2770

2769

2760

2751

What goes into the envelope?

- Participants collect unwanted medicine from their home
- They leave medicine in the original bottles (if possible) and put the bottles in the envelope according to the instructions
- Participants also fill out a survey and put it in the envelope

What happens to the medicine?

- The Maine Drug Enforcement Agency receives the envelopes with the medicine
- The medicine is cataloged by project pharmacists and safely destroyed



Calling the Program Helpline

- After participants have mailed the envelope, they will need to call the Program Helpline at **1-866-637-9743** and leave a message with the envelope code number and date they mailed the envelope



Program Partners and National Advisory Board

Maine-Based Organizations

- Center on Aging, University of Maine
- Maine Association of Psychiatric Physicians
- Maine Benzodiazepine Study Group (MBSG) & Drug Disposal Group
- Maine Council for Child & Adolescent Psychiatry
- Maine Department of Health and Human Services
- Maine Department of Environmental Protection
- Maine Drug Enforcement Agency
- Maine Office of Adult Mental Health Services
- Maine Office of Substance Abuse
- Maine Center for Disease Control and Prevention
- Maine Office of the Attorney General
- Maine Office of Elder Services
- Maine Pharmacy Association
- Maine Independent Pharmacies
- Maine RSVP Programs

- Margaret Chase Smith Center Policy Center, University of Maine
- Northern New England Poison Center

Federal & National Organizations

- American Pharmacists Association
- Community Medical Foundation for Patient Safety
- National Council on Patient Information and Education
- Office of the U.S. Attorney General
- Rite Aid Corporation
- U.S. Drug Enforcement Administration
- U.S. Environmental Protection Agency
- U.S. Postal Service
- Villanova University Center for the Environment



Safe Medicine Disposal for ME:

Funded by the U.S. EPA Aging Initiative

Program goals:

- Remove unneeded prescription drugs from circulation by providing an environmentally safe way to dispose of medications.

Environmental impact of pharmaceuticals:

- Studies are revealing negative environmental impacts on water quality and aquatic life from flushed medications.

Facts about Teens and Rx Abuse:

- Many teens believe that prescription drugs are safer than alcohol or illicit drugs, and that abusing them isn't risky.
- "Pharm Parties" are where teens dump bottles of prescription medications into a punch bowl and ingest random medications to get "high".

Medication Safety:

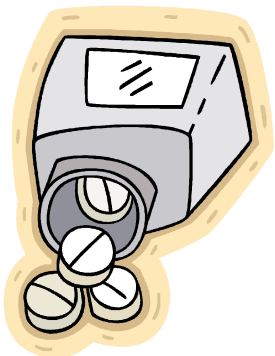
- Some poisonings reported to poison control centers come from the accidental ingestion of medications that have been left unsupervised and within the reach of children.
- Home burglaries related to prescription drugs are on the rise.

Remember to:

- Review the contents of your medication cabinet regularly.
- Check the expiration dates on your prescription and nonprescription medications.
- Store medications safely, out of the reach of children and in a locked cabinet if possible.

How you can safely dispose of medications:

- Utilize the Safe Medicine Disposal for ME program. Call the program helpline at **1-866-637-9743** for more information. Or email: info@safemeddisposal.com.
- Contact your local law enforcement office to see if they sponsor a medication take-back event or drug drop-off day in your community.
- Contact the Northern New England Poison Control Center at **1-800-222-1222** for other safe disposal options and to add medication take-back event dates to their informational calendar.



Information gathered with thanks from:

National Council for Patient Information and Education
U.S. Environmental Protection Agency
Northern New England Poison Control Center
Maine Department of Environmental Protection
Maine Office of Substance Abuse Services
Maine Benzodiazepine Study Group
Project AWARE

Safe Medicine Disposal for ME Community Education Presentation

Instructions: This survey form was developed to find out levels of awareness that the general public has of prescription medication issues. Each audience member can complete the questionnaire. The information collected by the evaluation helps to improve these types of community education programs.

1. Today's Date: ____/____/____ (MO/DD/YYYY)
2. What county was this presentation provided in?: (please fill in the blank below)

3. Your Age:
 ____ 19 or under ____ 20-29 ____ 30-39 ____ 40-49
 ____ 50-59 ____ 60-69 ____ 70-79 ____ 80 and over
4. Your gender: ____ Male ____ Female
5. Have you ever participated in a community take back/drug drop off program to dispose of unwanted medications? (Please circle one) YES NO
6. Overall, how would you rate this presentation: (circle one)
 Needs Improvement OK Good Excellent
7. Comments: _____

Respond to each of the following statements below by circling either TRUE or FALSE in the box next to the statement.

| | | |
|---|------|-------|
| 1. It is important to discard any unused or expired medications in my home. | TRUE | FALSE |
| 2. It is important to discuss the dangers of prescription medications with family members. | TRUE | FALSE |
| 3. Proper disposal of medications protects the environment and keeps people safe. | TRUE | FALSE |
| 4. Prescription painkillers are not addictive because doctors prescribe them. | TRUE | FALSE |
| 5. Prescription drug abuse is not a problem in Maine. | TRUE | FALSE |
| 6. Many teens believe that prescription drugs are safer than alcohol or illicit drugs, and that abusing them is <u>not</u> risky. | TRUE | FALSE |
| 7. Flushing medications does not harm the environment. | TRUE | FALSE |
| 8. Medicine has an expiration date similar to food that you should pay attention to. | TRUE | FALSE |

Thank you! Please give this sheet to your presenter before you leave.

Presentation Guidelines for “Safe Medicine Disposal for ME” Volunteer
Community Education Presentations

Setting up a speaking event:

1. Arrange speaking opportunity with a community group – inform Jen about date, time, place, and audience size
2. Ideal audience size is 10-15 people
3. Plan on a total meeting time of 30 minutes (allowing time for discussion)
4. Use a round-table approach if possible
5. Distribute the handouts/pamphlets to audience members before you start
6. Go through the presentation slides with the audience – demonstrate the use of the envelopes at the end of the presentation
7. Have audience members fill out an evaluation form and pass them in to you before they leave – in exchange they will receive an envelope
8. If possible, take pictures at the event

Materials checklist:

1. Copy of the presentation for you to speak from
2. Sign-in sheet
3. Educational pamphlets/handouts
4. Evaluation forms
5. Drug return envelopes
6. Pens
7. Camera (you supply)
8. “Safe Medicine Disposal for ME” name badge (previously given)

Presentation flow:

1. Introduce yourself as a “Safe Medicine Disposal for ME” volunteer
2. Have the audience members fill out the sign-in sheet
3. Inform audience members that your goal is to provide them with information about medication safety and the “Safe Medicine Disposal for ME” program
4. Distribute educational materials and the evaluation form to the audience and begin the presentation by following the presentation outline
5. At the end, demonstrate how to use the drug return envelopes
6. Have audience members fill out evaluation forms and in exchange for a completed evaluation they will receive an envelope
7. Thank them for their participation



RSVP



Safe Medicine Disposal for ME Program

RSVP VOLUNTEER HOURS *Self-Reporting Timesheet* COMMUNITY VOLUNTEERS

Name _____
Address _____

To be completed by the RSVP Volunteer:

| Volunteer Activity/Location | Hours | Date |
|-----------------------------|-------|-------|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| Total Hours | _____ | |

Volunteer Signature _____

Signature of On-Site Contact Person _____

Please return at the end of the month to:

UMaine Center on Aging
RSVP
Camden Hall
25 Texas Avenue
Bangor, Maine 04401-4324

APPENDIX GROUP 9

Marketing & Outreach Items

- APPENDIX GROUP 9: Marketing and Outreach Materials
 - APPENDIX 9A: Consumer fact sheet
 - APPENDIX 9B: Detailed fact sheet
 - APPENDIX 9C: Program brochure
 - APPENDIX 9D: Program summary sheet
 - APPENDIX 9E: Program business cards
 - APPENDIX 9F: April 2007 program press release
 - APPENDIX 9G: July 2009 program press release
 - APPENDIX 9H: Sample press release for local communities
 - APPENDIX 9I: Save the date announcement for the 2008 International Symposium on Pharmaceuticals in the Home and Environment
 - APPENDIX 9J: Save the date announcement for the 2009 International Conference on Safe Medicine
 - APPENDIX 9K: List of program-related publications and presentations

Safe Medicine Disposal for ME Program

Do you have unwanted or expired prescription medicine in your home?

Many people do not use all of the medicine they were prescribed. It is important to get rid of your unwanted or expired medicine safely.



This can help prevent:

- Accidental poisoning of children, grandchildren, and pets
- Intentional misuse by teenagers and adults—even people you know
- Health problems from taking the wrong medicine, too much of the same medicine, or a medicine that is too old to work well
- Theft of the medicine by drug users who may break into your home



You can get rid of your unwanted or expired medicine in a way that keeps people safe and helps keep leftover prescription medicine from getting into Maine's water supply and environment.

Some options include:

- A medicine disposal program by mail, like *Safe Medicine Disposal for ME*. This program provides Maine residents of all ages with a special envelope to mail unwanted or expired prescription medicine for safe disposal.
- A community medicine drop-off event. You can find out if there is a program in your area by contacting Northern New England Poison Center at 1-800-222-1222. You can also call them to get help identifying your medicine or for medicine-related concerns.
- Talking to your pharmacist or local law enforcement about other safe options



For more information about safe medicine disposal, contact:

Safe Medicine Disposal for ME

1-866-ME-RX-RID

(1-866-637-9743)

info@safemeddisposal.com

www.safemeddisposal.com





Safe Medicine Disposal for ME Program

Based on figures from the National Unused and Expired Medicine Registry, as many as 40% of prescription medicines are never used. Such medicines represent an expensive waste of healthcare resources and a potential environmental and safety hazard.

Unused Prescription Medicine is: An Environmental and Health Hazard

- Over half of Americans dispose of unwanted prescription medicine in the trash, one-third put it down the sink or toilet, and *only 1.4% return it to a collection facility*.¹
- Prescription medicine then enters the water through disposal down a drain or from the leaching or leaking of the drugs from landfills.²
- Over 80 pharmaceuticals of various prescription drug classes have been found in treated sewage, surface water, and ground water throughout the country.³
- Studies have found that exposure to medicine in water has been linked to serious reproductive side effects in fish, and the full effect on humans is currently unknown.⁴

A Danger to Children and Pets

- Children and pets can accidentally get poisoned by unused prescription medicine found in the home.
- In the US, medicine in the home accounts for more accidental poisonings than any other product.⁵
- Nearly 2% of children ages 12-13 intentionally misuse prescription medicine.⁶ Accessibility to the medicine is likely a contributing factor to this growing trend.⁷

A Danger to Older Adults

- Older adults make up only 13% of the population, but fill one-third of all prescriptions. This makes them susceptible to intentional or accidental medicine misuse, dependence, and addiction.⁸
- Diversion and theft of prescription medicine is currently at very high levels, and older adults may be particularly at risk.⁹

A Danger to Communities

- In 2002 in Maine, almost *90% of all drug deaths* were caused by prescription medicine.¹⁰
- The non-medical use of prescription medicine, among US residents ages 12 and older, is more common than the use of any illicit drug except marijuana.¹¹
- Maine DEA arrests for prescription medicine misuse have increased dramatically to 16% of all arrests.¹²

A Waste of Valuable Healthcare Dollars

- One small study conservatively estimates the cost of wasted prescription medicine by adults ages 65 and older to be *over one billion dollars annually*.¹³
- With healthcare costs rising at 3 times the rate of inflation, this waste will only continue to grow.¹⁴

For more information contact Safe Medicine Disposal for ME

1-866-637-9743



References:

Introduction paragraph: Mireles, M. (2008). National Unused and Expired Medicine Registry. Unpublished data. Bellaire, Texas: Community Medical Foundation for Patient Safety.

1. Bound, J. & Voulvoulis, N. (2005). Household disposal of pharmaceuticals as a pathway for aquatic contamination in the United Kingdom. *Environmental Health Perspectives (electronic version)*, 113(12), 1705-1711.
2. Northwest Product Stewardship Council. (2006). *Pharmaceuticals and product stewardship*. Retrieved from www.productstewardship.net/productsPharmaceuticals.html on 9/12/2006.
3. Heberer, T. (2002). Occurrence, fate, and removal of pharmaceutical residues in the aquatic environment: A review of recent research data. *Toxicology Letters*, 131, 5-17.
4. Disposal of unused medicines- Concern grows over environmental impacts. (2004). *Journal of Environmental Health*, 66(10), 42.
5. Northwest Product Stewardship Council. (2006). *Pharmaceuticals and product stewardship*. Retrieved from www.productstewardship.net/productsPharmaceuticals.html on 9/12/2006.
6. National Institute on Drug Abuse (2006). Trends in prescription drug abuse. *Research Report Series. Prescription Drugs: Abuse and Addiction*. Retrieved from <http://www.drugabuse.gov/ResearchReports/Prescription/prescription5.html#Older> on 3/9/2007.
7. National Institute on Drug Abuse (2005). Prescription drugs. *NIDA Community Drug Alert Bulletin*. Retrieved from <http://www.drugabuse.gov/PrescripAlert/> on 3/9/2007.
8. National Institute on Drug Abuse (2006). Trends in prescription drug abuse. *Research Report Series. Prescription Drugs: Abuse and Addiction*. Retrieved from <http://www.drugabuse.gov/ResearchReports/Prescription/prescription5.html#Older> on 3/9/2007.
9. U. S. Drug Enforcement Administration (2006). *Pharmaceutical Drugs*. Retrieved from <http://www.usdoj.gov/dea/concern/18862/pharm.htm> on 3/9/2007.
10. Department of Health and Human Services, Office of Substance Abuse (2005). *Maine's Prescription Monitoring Program*. Retrieved from www.maine.gov/dhhs/osa/data/pmp on 9/18/2006.
11. Substance Abuse and Mental Health Services Administration. (2006). *Results from the 2005 National survey on drug use and health: National findings*. Rockville, MD: Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194.]
12. Department of Health and Human Services, Office of Substance Abuse (2005). *Maine's Prescription Monitoring Program*. Retrieved from www.maine.gov/dhhs/osa/data/pmp on 9/18/2006.
13. Morgan, T. (2001). The economic impact of wasted prescription medication in an outpatient population of older adults. *Journal of Family Practice (electronic version)*, 50(9), 779-781.
14. National Coalition on Health Care (2006). *Facts on Health Care Costs*. Retrieved from <http://www.nchc.org/facts/cost.shtml> on 3/12/2007.



PROGRAM PARTNERS INCLUDE:

- University of Maine Center on Aging
- U.S. Environmental Protection Agency
- U.S. Postal Service
- Community Medical Foundation for Patient Safety
- Rite Aid Pharmacies
- Safe Medicine for Maine
- Maine Department of Environmental Protection
- Maine Drug Enforcement Agency
- U.S. Drug Enforcement Administration
- Maine Office of Adult Mental Health
- Maine Office of Elder Services
- Maine Office of Substance Abuse
- Maine Office of the Attorney General
- Maine Pharmacy Association
- Maine RSVP Programs
- Margaret Chase Smith Policy Center
- National Council on Patient Information and Education
- Northern New England Poison Center
- Miller Drug
- Maine Department of Health and Human Services
- Maine Association of Psychiatric Physicians
- Maine Council for Child and Adolescent Psychiatry
- CVS Pharmacies
- Maine Medical Association
- Villanova University Center for the Environment
- Community organizations and pharmacies throughout Maine

SAFE MEDICINE DISPOSAL FOR ME

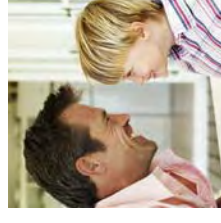
Envelopes are now available throughout Maine. Please check our website for regular updates on site locations where you can obtain an envelope as well as upcoming special community events.

INFORMATION:

For a complete listing of sites visit our website at: www.safemeddisposal.com

call: 1-866-637-9743

or e-mail: info@safemeddisposal.com



**A disposal program for all
Maine residents!**



Funded through a Fund for Healthy Maine
allocation to the Maine Drug Enforcement Agency

© 2009

University of Maine Center on Aging
Camden Hall, 25 Texas Ave, Bangor, Maine 04401

WHAT IS SAFE MEDICINE DISPOSAL FOR ME?

Safe Medicine Disposal for ME is an easy, anonymous way for Maine's citizens to safely and properly get rid of unused or expired medicine.



HOW MUCH DOES IT COST?

Nothing! It is FREE to participate. Safe Medicine Disposal for ME has already paid for the envelopes and postage.

Just follow the instructions, and the envelopes are ready to go!

Donations are accepted. Please call the program helpline if you would like to contribute.

HOW DOES IT WORK?

- Postage-paid medicine return kits are distributed to participating sites across the state
- Kits including an envelope and instruction packet are given by request to interested individuals
- Participants follow the enclosed instructions to place unused medications in the envelope
- Envelopes are returned by mail to the Maine Drug Enforcement Agency and then safely destroyed

WHAT ARE THE BENEFITS?

- Minimize accidental overdoses and poisonings of:



- * Older Adults
- * Children
- * Teenagers
- * Pets

- Limit illegal diversion of prescription drugs and drug-related thefts and crimes

- Decrease opportunities for drug abuse
- Prevent environmental exposure to protect Maine's water and wildlife
- Help reduce waste in the health care system

WANT TO PARTICIPATE?

Envelope kits are available free of charge while supplies last at participating sites. Program envelopes are available at participating locations throughout Maine.

For up-to-date information on program sites in your area visit:

www.safemeddisposal.com

call: 1-866-637-9743

or

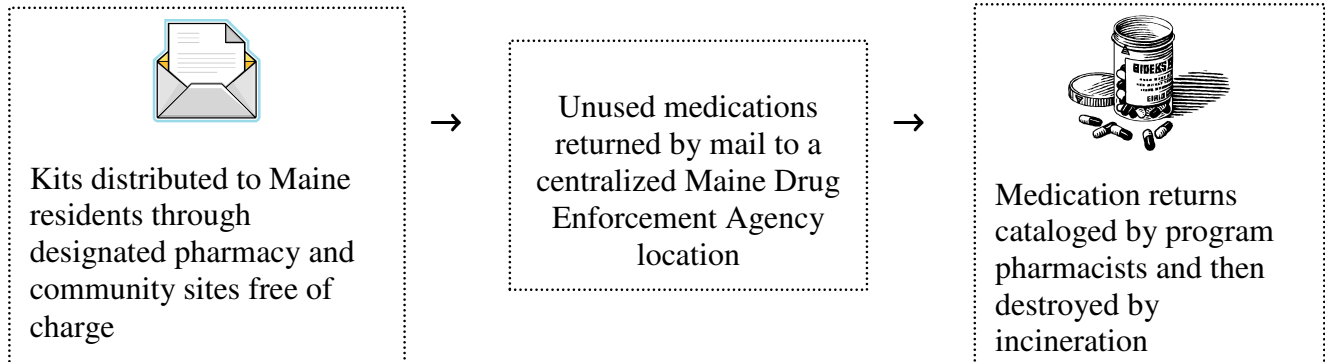
e-mail: info@safemeddisposal.com

Safe Medicine Disposal for ME Program



The University of Maine Center on Aging has received funding through a Fund for Healthy Maine allocation from the Maine Drug Enforcement Agency to operate Maine's prescription drug-return-by-mail program, the first of its kind in the country.

Program Take-Back Model at a glance:



Why Maine?

- Maine has the oldest population in the nation as measured by median age. Americans age 65 and older account for over one-third of all prescription drugs dispensed, despite making up only about 13% of the national population.
- The state of Maine has previously experienced and documented the consequences of unused drugs remaining in circulation. In 2002, nearly 90% of all drug deaths in Maine were caused by prescription drugs. Maine DEA arrests for prescription drug theft and misuse have increased dramatically to 16% of all arrests in the state. Maine ranks number one in the country in terms of the relationship of pharmaceuticals to violent crime and property crime.

What are the benefits of this model?

Many other areas of the country are considering replicating our model of drug disposal. Here's why:

- Avoids the harmful environmental impacts and health hazards of flushing or disposing of drugs via household trash
- Easy, convenient, and anonymous way of disposing of drugs
- Takes advantage of the security protocols of the U.S. Postal Service mail system
- Accessible to those who live in rural areas and are unable to attend event-based or on-site medicine return programs

- Drugs are returned directly to the Maine Drug Enforcement Agency so the program is able to accept controlled substances
- From a social standpoint such a program presents the opportunity to: limit drug related crimes, limit opportunities for drug abuse, and reduce waste related to medical and insurance costs by providing a safe alternative from stockpiling medications in consumer's homes
- The potential environmental benefits include: protecting water and soil supplies from drug contamination and prevention of accidental poisonings of humans, pets, and wildlife

This initiative is a unique collaboration between environmental, drug enforcement, and healthcare officials and puts the University of Maine in the forefront of innovative outreach research. Lessons learned through this program can be used to shape state and national public policy, physician prescribing practices, and health education outreach strategies.

Program Partners:

Program partners include the: University of Maine Center on Aging, United States Environmental Protection Agency, United States Postal Service, Community Medical Foundation for Patient Safety, Safe Medicine for Maine, Maine Department of Environmental Protection, Maine Drug Enforcement Agency, U.S. Drug Enforcement Administration, Rite Aid Pharmacies, Maine Office of Elder Services, Maine Office of Substance Abuse, Maine Association of Psychiatric Physicians, Maine Office of the Attorney General, Maine Pharmacy Association, Maine RSVP Programs, Margaret Chase Smith Policy Center, National Council on Patient Information and Education, Miller Drug, Maine Department of Health and Human Services, CVS Pharmacies, Maine Office of Adult Mental Health Services, Maine Medical Association, Northern New England Poison Center, Villanova University Center for the Environment, Maine Council for Child and Adolescent Psychiatry, University of New England and community organizations and pharmacies throughout Maine.

Program Contacts:

Website: www.safemeddisposal.com
 E-Mail: info@safemeddisposal.com
 Phone: 1-866-637-9743



A diagram illustrating the flow of information. It starts with a container (like a pill bottle) on the left, followed by a large grey arrow pointing to a square icon of an envelope with a letter inside. Another large grey arrow points from the envelope icon to a mailbox on the right.

E-mail: info@safemeddisposal.com

A diagram illustrating the flow of information. It starts with a container (like a bottle or can) on the left, followed by a right-pointing arrow to an envelope icon in the middle, and another right-pointing arrow to a mailbox icon on the right.

E-mail: info@safemeddisposal.com

The diagram illustrates a process flow. It starts with a container (like a pill bottle) on the left, followed by a right-pointing arrow to a square box containing an envelope icon. Another right-pointing arrow leads from the square box to a mailbox icon on the right.

E-mail: info@safemeddisposal.com

The diagram illustrates the flow of information. It starts with a container (like a bottle or can) on the left, followed by a large arrow pointing to an envelope in the middle, and another large arrow pointing to a mailbox on the right.

E-mail: info@safemeddisposal.com

A diagram illustrating the flow of information. It starts with a pill bottle on the left, followed by a large grey arrow pointing to a square icon containing an envelope. Another large grey arrow points from the envelope icon to a mailbox on the right.

E-mail: info@safemeddisposal.com

A diagram illustrating the process flow: a bottle of medicine is shown on the left, followed by a right-pointing arrow leading to an envelope icon, which is followed by another right-pointing arrow leading to a mailbox icon.

E-mail: info@safemeddisposal.com

E-mail: info@safemeddisposal.com

E-mail: info@safemeddisposal.com

A diagram illustrating the flow of information. It starts with a pill bottle on the left, followed by a large grey arrow pointing to a square icon containing an envelope. Another large grey arrow points from the envelope icon to a mailbox icon on the right.

E-mail: info@safemeddisposal.com

The diagram illustrates the flow of information. It starts with a container (like a bottle or jar) on the left, followed by a large arrow pointing to an envelope in the middle, and another large arrow pointing to a mailbox on the right.

E-mail: info@safemeddisposal.com

Rx Drug Mail Back Program Comes to Your Community!

Ever wondered how to dispose of expired or unused prescription medicine? Now, thanks to the Safe Medicine Disposal for ME Program, disposing of prescription medicine has never been safer or easier. The program provides postage-paid mailing kits to participating pharmacies in the area. Patrons can pick up these kits and then mail their unused medicine to the Maine Drug Enforcement Agency for proper disposal.

The Safe Medicine Disposal for ME Program, funded by the Environmental Protection Agency and other state partners, helps to ensure that unused medicine does not harm Maine's waterways or wildlife and also ensures that medicine is not available for misuse.

This free program is available at the following COUNTY NAME HERE locations and is open to all Maine residents:

LIST SITES HERE

Simply go to one of the pharmacies on this list to get your mail back kit. Each kit comes with instructions and postage paid mailer. If you would like more information please contact the program by phone or email at 1-866-637-9743, info@safemeddisposal.com or online at www.safemeddisposal.com

For Conference Information Contact:

Jason Charland, Conference Coordinator
UMaine Center on Aging

Telephone: 207.262.7928

jason.charland@umit.maine.edu

Register online at:

www.mainebenzo.org

**2008 SYMPOSIUM ON
PHARMACEUTICALS IN THE HOME
AND ENVIRONMENT:
CATALYSTS FOR CHANGE**

**The 2008 International Symposium on
Pharmaceuticals in the Home and
Environment: Catalysts for Change**

Monday-Tuesday
November 10-11, 2008
Wyndham Hotel Portland Airport
South Portland, ME

This year's conference will be the gathering place for disseminating the latest trend data available on prescription issues including:

- * Drug diversion, fraud, prevention, and abuse
- * Innovative national and international prescription drug return and disposal programs
- * Medication management and prescribing
- * And much, much more!

Registration fees

2 days \$199 (*students = \$150*)

1 day \$119 (*students = \$75*)

Wyndham Hotel Portland Airport
363 Maine Mall Road
South Portland, ME 04106

1-800-996-3426 (1-800-WYNDHAM)

www.mainebenzo.org

*Group Code: UMaine Center on Aging
Group Room Rate: \$94. + tax*

Get your Continuing Education Credits before 2008 ends!

Continuing Education Details:

The University of New England is accredited by the American Osteopathic Association and the Maine Medical Association to provide continuing medical education for physicians.

- UNE designates this educational activity for a maximum of 11.0 Category 2A osteopathic, and 11.5 *AMA PRA Category 1 Credits*TM.
- Approved for 11.5 University contact hours (1.2 CEUs) by the University of New England.
- CEUs pending for Maine Boards of Pharmacy and Social Work Licensure
- Certificates of attendance will be provided

Conference Sponsors:

MeHAF 
Maine Health Access Foundation



**RECKITT
BENCKISER**

 **THE BINGHAM PROGRAM**

www.mainebenzo.org

SAVE THE DATE!

**Sunday-Tuesday
October 18-20, 2009**

2009 International Conference on Safe Medicine

*Point Lookout Resort and Conference Center
Northport, Maine*



- **Meet** with the leading authorities on prescription drug use, abuse, return and disposal
- **Attend** cutting edge educational symposia and panel sessions
- **Build your skills** at expert-led, pre-conference, technical assistance workshops
- **Participate** in lively specialized topic interest groups
- **Enjoy** the special networking opportunities, exhibits, and annual film festival

Call for proposals, films, and exhibitors coming soon!

For more information contact:

Maine Benzodiazepine Study
Group
& Drug Disposal Group
UMaine Center on Aging
Phone: 207-262-7922
Email: mbsg@mainebenzo.org



**Program-Related Publications and Presentations
(Chronological order)**

- Fredrix, E. (2007, July 26). Pharmaceutical disposal companies turn unwanted drugs into power. *Milwaukee Associated Press*. Available online at: www.examiner.com.
- Booth, G.C. (August 2007). Unused drugs in Maine to be mailed, incinerated. *Raymond Communications' Recycling Policy News*. Available online at: www.raymond.com
- Miller, K. (2007, September 27). New program aims to stop pill pollution. *Bangor Daily News*. Available online at: www.bangornews.com.
- University of Maine. (September-October edition). Safe return. *UMaine Today*, p. 28.
- Hayward, M. (2007, October 4). Cleaning up the right way: UM research reduces water pollution from discarded pills. *The Maine Campus*. Available at: www.mainecampus.com.
- Associated Press (2007, November 5). Mix leftover meds with kitty litter: Experts say icky disposal method safer for kids and environment. *MSNBC*. Available at: <http://www.msnbc.msn.com/id/21641396/print/1/displaymode/1098/>
- US EPA Aging Initiative. (November 2007). Safe Medicine Disposal for ME project update and summary of Maine drug disposal efforts. *Aging Initiative Listserve*. E-mail communications.
- Community Medical Foundation for Patient Safety. (2008, March 4). *Forty percent of prescription medicines are thrown away—It is time to check your medicine cabinet and think about safe medication practice* (press release). Available at: www.communityofcompetence.com.
- Donn, J., Mendoza, M., & Pritchard, J. (2008, March 11) Little done to test, limit contaminated water. *USA Today*. Available at: www.usatoday.com.
- Richardson, J. (2008, March 14) Disposing of drugs: Help is on the way. *Portland Press Herald*. Available at: www.pressherald.com.
- Peckenham, J. (2008, March 20) On a mission for safe water. *Bangor Daily News*. Available at: www.bangornews.com.
- Lunn, H. (March 28, 2008). *Safe Medicine Disposal for ME demonstration and overview*. Presentation at the Knox County Community Health Coalition, Camden, ME. (Approx 75 people in attendance)
- Maine Department of Environmental Protection. (2008, May 9). *Avoid flushing medications in our back yard*. Press Release.

Safe Medicine Disposal for ME program feature. (2008, May 16). *WABI TV 5 News*. [Maine Television News Program].

University of Maine Center on Aging initiatives. (2008, May 31). *Senior Talk with Carol Higgins*. [Radio Program].

Dolloff, A. (2008, June 5). Maine leading nation in Rx drug mail-back. *Bangor Daily News*, available online at www.bangornews.com.

Hayward, N. (June 5, 2008). *Safe Medicine Disposal for ME program demonstration and overview*. Presentation at the Washington County Cooperative Extension's Senior Companion Program Meeting, Washington County, ME. (Approx 15 people in attendance)

Huang, J. (2008, June 7). Mainers get more ways to discard unwanted pills. *Portland Press Herald*. Available online at: www.pressherald.com.

Lunn, H. (June 11, 2008). *Safe Medicine Disposal for ME overview*. Presentation at the Healthy and Safe Living Event for Mature Adults, Rockland, ME. (Approx 25 people in attendance)

Dangers of unused drugs getting more attention in Maine. (2008, June 12). *Portland Press Herald*. Available online at: www.pressherald.com.

Washington County Cooperative Extension Senior Companion Program. (June 12, 2008). *Safe Medicine Disposal for ME program overview and follow-up information session*. Program presentation, Washington County, Maine.

Kaye, L. W. (June 14, 2008). *Safe Medicine Disposal for ME program presentation*. Presentation at the Eastern Area Agency on Aging Medicare Event, Bangor, Maine.

Kocian, L. (2008, June 15). Getting rid of what the doctor ordered: Proper disposal of unwanted medications is daunting, costly. *Boston Globe*. Available online at www.globe.com.

Safe Medicine Disposal Program initiated. (June 18, 2008). *Machias Valley News Observer*, page 24.

Crittenden, J. A. (June 24, 2008). *Safe Medicine Disposal for ME program overview*. Panel presentation at the Oregon Drug Take Back Program Convening Meeting, Portland, OR.

Longley, C., & Payne, B. (June 27, 2008). *Safe Medicine Disposal for ME program information table and mailing list sign-up*. Presentation at the Oxford County TRIAD Senior Citizen Picnic, Oxford County, ME.

Chaitman, S. (2008, July 9). MWRD eyes study on drugs in water. *Chi Town Daily News*. Available online at: www.chitowndailynews.org.

- Maguire, J. (2008, August 6). Drug disposal dilemma. *Lincoln County News*. Available online at: www.mainelincolncountynews.com.
- Broderick, R. (September 2008). Waste not: Managing Minnesota's hazardous medical waste is a complicated task. *Minnesota Medicine*. Available online at: www.minnesotamedicine.com.
- Kaye, L. W. (September 5, 2008). Safe Medicine Disposal for ME program overview. Presentation at the Maine Health Access Foundation Medication Stakeholder Group Meeting, Augusta, ME.
- Charland, J. (September 11, 2008). *Pilot testing of the Safe Medicine Disposal for ME community education curriculum*. Presentation at the Calais Regional Hospital Seniority Group, Calais, ME.
- Kaye, L. W. (September 11, 2008). *Implementation of the Safe Medicine Disposal for ME Prescription mail-back program*. Presentation at the Society for Human Ecology Conference, Bellingham, WA.
- Gressitt, S. (October 6, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 3, Augusta, ME.
- Gressitt, S. (October 9, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 7, Biddeford, ME.
- Gressitt, S., & Crittenden, J. A. (October 11, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Pharmacy Association Conference, Rockland, ME.
- Gressitt, S. (October 13, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 4, Rockland, ME.
- Gressitt, S. (October 14, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Maine Office of Adult Mental Health Community Service Network # 2, Bangor, ME.
- Nathanson, B. (October 14, 2008). *Safe Medicine Disposal for ME informational table*. Penquis RSVP Annual Recognition Luncheon, Bangor, ME.
- Marston, H. (October 16, 2008). *Safe Medicine Disposal for ME information and community education session*. Presentation at Stella Maris Apartments, Rockland, ME.

- Longly, C., & Payne, B. (October 17, 2008). *Safe Medicine Disposal for ME information table*. Presentation at the Oxford County TRIAD, Rumford, ME.
- Davis, S. (October 20, 2008). *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Bucksport Meals for ME Site, Bucksport Senior Center, Bucksport, ME.
- Gressitt, S. (October 20, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 5, Lewiston, ME.
- Gressitt, S. (October 23, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 5, Presque Isle, ME.
- Staples, B. (2008, November 3). Agencies to assist with safe medicine disposal. *Village Soup-Waldo County*, available online at <http://waldo.villagesoup.com>.
- Kaye, L.W., Crittenden, J. A., Gressitt, S., & McKinney, R. (November 10, 2008). *EPA projects symposium panel*. Moderated by Kathy Sykes, 2008 International Symposium on Pharmaceuticals in the Home and Environment, Portland, ME.
- Nathanson, B. (November 13, 2008). *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Waldo County TRIAD, Belfast, ME.
- Matulis, P., & Matulis, N. (November 20, 2008). *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Piscataquis Regional YMCA, Dover-Foxcroft, ME.
- Gressitt, S. (November 21, 2008). *Safe Medicine Disposal for ME overview, policy and practice implications*. Presentation at the Maine Office of Adult Mental Health Community Service Network # 6, Portland, ME.
- Pistell, A. (November 21, 2008). *Mailback as a drug disposal model*. Presentation for the Product Stewardship Institute, Conference Call.
- Crittenden, J.A., Kaye, L.W., Charland, J.C., & Gressitt, S. (November 22, 2008). *What's in your medicine cabinet?: Preliminary data from the first year of the Safe Medicine Disposal for ME Program*. Presentation at the 61st Annual Scientific Meeting of the Gerontological Society of America, National Harbor, MD.
- Burnett, P., Charland, J.C., Kaye, L. W., & Crittenden, J.A. (November 23, 2008). *Engaging older adult volunteers in high impact activities aimed at reducing pharmaceuticals in the environment*. Presentation at the 61st Annual Scientific Meeting of the Gerontological Society of America, National Harbor, MD.

- Crittenden, J. A., & Kaye, L. W. (November 24, 2008). *Implementing a consumer pharmaceutical mailback program: An analysis of the Safe Medicine Disposal for ME Program*. Presentation at the 61st Annual Scientific Meeting of the Gerontological Society of America, National Harbor, MD.
- National Able Network. (December 2008). Did you know?: Safe Medicine Disposal for ME. *Able Times*, 1 (1), pg. 2.
- Gressitt, S., Kaye, L.W., Crittenden, J. A., & Bullard, L. (December 3, 2008). *Maine unused drug disposal project*. Presentation at the CDC Promising Legal Responses to the Epidemic of Prescription Drug Overdoses in the United States, Atlanta, GA.
- Gressitt, S. (December 9, 2008). *Safe medicine disposal*. Panel presentation at the Maine Rural Water Association Conference, Freeport, ME.
- Huang, J. (2008, December 29). Maine program offers mail-in option for unused drugs. *Maine Public Broadcasting Network*. Available online at www.mpbnet.net.
- Richardson, J. (2008, December 29). Maine pilots eco-friendly way to dispose of drugs; Backers, who say it will prevent abuse, want drug makers to pay the cost. *Portland Press Herald*. Available online at: www.pressherald.com.
- DeGrenier, L. (January 15, 2009). *Safe Medicine Disposal for ME overview and community education session*. Presentation at the Bangor YMCA Caring Connections Bone Health Group, Bangor, ME.
- Lunn, H. (February 3, 2009). *Safe Medicine Disposal for ME program update*. Presentation at the Knox County Community Health Coalition, Rockland, ME.
- Kaye, L.W. (February 3, 2009). *Environmental consciousness and reducing prescription drug misuse through the use of a citizen mail-back program*. Keynote presentation at the Cornell University Aging and Environment Seminar, Ithaca, NY.
- DeGrenier, L. (February 5, 2009) *Safe Medicine Disposal for ME Program Overview and Community Education Session*. Presentation at the Bangor House, Bangor, ME.
- Gressitt, S. (2009, February 5). Proper Drug Disposal. *WMPG FM Talk Radio*. [Radio Program].
- Lunn, H. (February 24, 2009) *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Rockland Methodist Retirement Home, Rockland, ME.
- DeGrenier, L. (February 25, 2009). *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Bangor YMCA Breast Cancer Support Group, Bangor, ME.

- Bowen, C. T. (2009, February 27). Prescription drugs need better controls. *St. Petersburg Times*. Available online at: www.tampabay.com.
- Stranahan, S.Q. (2009, February 27). Drugs in our drinking water: What do we do with unused medicines? *AARP Bulletin Today*. Available online at: <http://bulletin.aarp.org/>
- DeGrenier, L. (February 28, 2009). *Safe Medicine Disposal for ME program overview and community education session*. Presentation at the Eastern Maine Healthcare Toastmasters Group, Brewer, ME.
- Lunn, H. (March 5, 2009). *Safe Medicine Disposal for ME community education*. Presentation at the Rockland County TRIAD, Rockland, ME.
- Kaye, Lenard W. (April 14, 2009). *Testimony in support of 'An Act To Support Collection and Proper Disposal of Unwanted Drugs', LD 821 – item 1*. 124th Maine State Legislature, Testimony presented before the Maine State Legislature's Committee on Health and Human Services, Augusta, ME.
- Clement, K. (Spring 2009). Maine People Working Together To Keep Maine Green. *MaineLink*, Newsletter of the Maine Hospice Council.
- Lunn, H. (April 23, 2009). *Safe Medicine Disposal for ME Program overview and community education session*. Presentation at the Camden Senior Citizen Club, Camden, ME.
- Richardson, J. (2009, April 28). Pill-disposal idea hard for drug companies to swallow. *Portland Press Herald*. Available online at: www.pressherald.com.
- Davis, S. (May 14, 2009). *Safe Medicine Disposal for ME Program overview and community education session*. Presentation at Gardner Commons, Bucksport, ME.
- Gressitt, S. (May 23, 2009). *Maine unused medicine mail back pilot summary*. Presentation at the 4th International Symposium on Environment, Athens, Greece.
- Lunn, H. (June 2, 2009). *Safe Medicine Disposal for ME Program overview and community education session*. Presentation at the Rockland Senior Citizens Club, Rockland, ME.
- Public Information Office, Maine Department of Public Safety (2009, June 18). 1,333 pounds of drugs returned. *Communicator*. Available online at: www.maine.gov.
- University of Maine (2009, July 13). *UMaine-based drug mail-back program refunded, expands*. *Press Release*.
- Haskell, M. (2009, July 21). Disposal plan for drugs to expand. *Bangor Daily News*. Available online at: www.bangornews.com.

- Kaye, L. W. (July 23, 2009). *Safe Medicine Disposal for ME: Volunteer involvement*. Presentation at Cornell University, Ithaca, NY.
- Safe Medicine Disposal for ME Program Feature. (2009, July 24). *MaineWatch*. [Maine Television News Program].
- Trenkner, T. (2009, August 17). More envelopes for unused meds. *Governing*. Available online at: www.governing.com.
- Gressitt, S., & Bullard, L. (September 5, 2009). *Mail model and findings of novel public unused pharmaceutical disposal program*. Presentation at the 69th World Congress of Pharmacy and Pharmaceutical Sciences, Istanbul, Turkey.
- Mireles, M., Filion, L., Crittenden, J. A., Miller, R., Hillman, R., & Helms, S. (October 18, 2009). *Organizing a drug collection program or event: Practical strategies and tips*. Pre-conference workshop at the 2009 International Symposium on Pharmaceuticals in the Home and Environment, Northport, ME.
- Kaye, L. W., Gressitt, S., Crittenden, J. A., & McKinney, R. (October 19-20, 2009). *Safe Medicine Disposal for ME: A project overview*. Poster presentation at the 2009 International Symposium on Pharmaceuticals in the Home and Environment, Northport, ME.
- Sykes, K., Kaye, L. W., Crittenden, J. A., Gressitt, S., McKinney, R., & Hillman, R. (October 19, 2009). *Safe Medicine Disposal for ME: Findings and recommendations from phases I & II*. Presentation at the 2009 International Symposium on Pharmaceuticals in the Home and Environment, October 19, 2009, Northport, ME.
- Kaye, L. W., Crittenden, J. A., Gressitt, S. (November 10, 2009). *Safe disposal of pharmaceuticals and personal care products: Current practices in the US*. Presentation at the 137th Annual Meeting of the American Public Health Association, Philadelphia, PA.
- Crittenden, J. A., Kaye, L. W., & Gressitt, S. (November 21, 2009). *Prescription drug return and disposal programming as a vehicle for older adult civic engagement*. Presentation at the 62nd Annual Scientific Meeting of the Gerontological Society of America, Atlanta, GA.
- Kaye, L. W., & Crittenden, J. A. (November 21, 2009). *Examining medicine accumulation and disposal: Drug profiles, influencing factors and policy implications for older adults*. Presentation at the 62nd Annual Scientific Meeting of the Gerontological Society of America, Atlanta, GA.